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ABSTRACT

This publication contains background readings on consumer affairs for students who are going to participate in the 1980-1981 national high school debate. The debate topic selected by the National Federation of State High School Associations is consumer protection. The three debate propositions are that the federal government should 1) initiate and enforce safety guarantees on consumer goods: 2) establish uniform standards for the regulation of commerical advertising: and 3) establish uniform standards for testing and marketing all products with potentially carcinogenic effects on humans. The first group of articles attempts to cover the area of consumer protection in general from a broad perspective giving historical information as well as addressing current issues. The next three sections contain background materials and essays on each of the debate positions. The articles included in each group begin with those dealing with the subject in general and then move on to those with a more specific focus. Those articles which deal with a pro and con aspect of an issue are grouped together so the reader can readily consider both sides of an issue. The compilers caution that, while the selections were chosen to reflect an overall balance on the debate topic any specific entry may represent a single point of view. Additional resources are listed. (Author/RM)

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How Can the Interests of United States Consumers Best Be Protected?

U.S. DEPARTMENT OF HEALTH,
EDUCATION & WELFARE
NATIONAL INSTITUTE OF
EDUCATION

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National Debate Topic for High Schools
1980-1981
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AN ACT To provide for the preparation and printing of compilation of materials relating to annual national high school and college debate topics

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Librarian of Congress is authorized and directed to prepare compilations of pertinent excerpts, bibliographical references, and other appropriate materials relating to (1) the subject selected annually by the National University Extension Association as the national high school debate topic and (2) the subject selected annually by the American Speech Association as the national college debate topic. In preparing such compilations the Librarian shall include materials which in his judgment are representative of, and give equal emphasis to, the opposing points of view on the respective topics.

SEC. 2. The compilations on the high school debate topics shall be printed as Senate documents and the compilations on the college debate topics shall be printed as House documents, the cost of which shall be charged to the congressional allotment for printing and binding. Additional copies of such documents may be printed in such quantities and distributed in such manner as the Joint Committee on Printing directs.

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FOREWORD

"How can the interests of United States consumers best be protected?" is the 1980-1981 high school debate topic selected by the National Federation of State High School Associations. The three debate propositions that have been designated within this topic are:

Resolved, That the Federal Government should initiate and enforce safety guarantees on consumer goods;

Resolved, That the Federal Government should establish uniform standards for the regulation of commercial advertising; and

Resolved, That the Federal Government should establish uniform standards for testing and marketing all products with potentially carcinogenic effects on humans.

This volume begins with a group of articles selected to provide an overview of consumer protection in general. It also contains separate groups of background materials and essays on each of the debate propositions. In choosing items for the collection and for the bibliography, the Congressional Research Service (CRS) attempted to sample the wide spectrum of opinions reflected in current literature on these issues. No preference for any policy is indicated by the selection or positioning of articles herein, nor should one infer CRS disapproval of any policy or article not included.

The coordination and final selection of articles and citations in this document was the responsibility of Mary Ann Keeffe, Analyst in Consumer Affairs in the Economics Division. Bruce K. Mulock, Analyst in the Economics Division, Geraldine Carr, Analyst in the Science Policy Research Division, and Legislative Attorney Henry Cohen in the American Law Division, were responsible for selecting references in their fields of expertise. The bibliography was drawn largely from the CRS Bibliographic Data Base with the assistance of Richard Gigax, Senior Bibliographer in the Library Services Division, who also prepared the notes and information on additional resources. Stephen Powitz in the Library Services Division and Mark Jickling, John Co[illegible]etta, and Gary Hauk in the Economics Division, helped in the administration of the project.

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Good luck to each debater in researching your topic and presenting your arguments.

GILBERT GUDE,
Director, Congressional Research Service.

INTRODUCTION

This manual is designed to facilitate research preparations for the 1980-81 high school debates. Following is information to help the debater make full use of the material included.

The first group of articles attempts to cover the area of consumer protection in general from a broad perspective giving historical information as well as addressing current issues. These articles should provide some useful concepts and data.

The remaining three groups are quite specific in nature: product safety, standards regulating advertising, and standards for testing and marketing potentially carcinogenic products. The articles included in each group begin with those dealing with the subject in general and then move on to those with a more specific focus. Those articles which deal with a pro and con aspect of an issue are grouped together so the reader can readily consider both sides of an issue.

In using this document, two points of caution should be noted. While the selections were chosen to reflect an over-all balance on the debate topic, any specific entry may represent a single point of view.

U.S. Government documents listed in the bibliography may be found in most U.S. Government depository libraries which can be identified by your public library. The Library of Congress cannot distribute copies of these or other materials to debaters.

Suggestions are included at the end of this volume on additional resources. Finally, there is included a list of relevant publications that are available for purchase from the Superintendent of Documents, Government Printing Office.

If several individuals wish to use the material in this volume, entire sections, articles, or pages can be removed easily by creasing the pages at the spine, then pulling them out.

HOW CAN THE INTEREST OF UNITED STATES CONSUMERS BEST BE PROTECTED?

This year's national high school debate topic has been the subject of many articles and much discussion for over a decade. Although consumer activists are disappointed over the failure to achieve the creation of an independent agency for consumer protection, the consumer movement in the United States has grown from almost nothing, 15 years ago, to an established force for change today. In the Federal area there have been notable actions, such as the passage of more than 50 new or expanded laws, regulatory-agency rulings, and creation of consumer affairs offices in all Cabinet-level departments, as well as in most independent agencies. Another indicator is the growth of consumer offices in State and local governments throughout the country. A major national opinion survey conducted in 1977 indicated that most Americans believe the consumer movement has significantly improved conditions in the marketplace in the past 10 years. Seventy-two percent of those polled said they believed their shopping skills had improved; 70 percent felt that labeling and product information had gotten better; and 60 percent believed that the safety of most products had improved.

Notably present in the discussion and debate on consumer protection has been much controversy on issues such as: whether protecting consumer interests should be the business of the Government or the job of the marketplace; and a large concern over the cost to taxpayers for operating so many Government functions and regulatory activities.

The following articles discuss these concerns and look into the consumer area in general, assessing accomplishments and failures, looking at particular issues, and projecting what might lie ahead.

CONSUMER PROTECTION: GAINS AND SETBACKS

THE AMERICAN CONSUMER movement has grown from virtually nothing 15 years ago to an established force for change today. There have been notable successes, such as the many federal laws and regulatory-agency rulings on consumer matters. But the movement also has been frustrated by a number of setbacks in recent years, including Congress's refusal to enact legislation setting up a federal consumer protection agency. In light of the setbacks, some wonder whether the consumer movement will ever again be as powerful and effective as it was in the late 1960s and early 1970s. "To assess such an amorphous thing as the consumer movement is not easy," Arthur E. Rowse, editor of *Consumer Newsweekly*, wrote recently. "There is no yardstick of progress. One can merely list gains and losses while trying to spot causes."[1]

Many consumer advocates say that Jimmy Carter's election has been a significant gain for the consumer movement. Carter spoke out strongly for consumer issues during the presidential campaign. He stressed his support for a strong government agency to represent consumers. In his presentation to the Democratic Party Platform Committee at the nominating convention, Carter called for "major reforms to protect the consumers of this country." A nationwide program of consumer education and vigorous enforcement of the nation's antitrust laws were two other Carter campaign promises.

During his first year in office, Carter placed some 60 former consumer and public interest activists in important positions in the government, a move highly praised by consumer groups *(see p. 136)*. In his State of the Union Address, delivered Jan. 19, 1978, Carter again said he was "strongly committed" to legislation creating a federal consumer protection agency. But despite White House support, the House voted down the measure on Feb. 8 *(see p. 126)*. White House Press Secretary Jody Powell said the following day, "It was a case of the best efforts on the part of the administration not being able to overcome some very organized and effective opposition" from business groups. Powell promised that "administration efforts on behalf of the consumer...will continue and intensify."

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[1] Rowse, former executive director of the White House Consumer Office, writing in *The Washington Post*, Dec. 25, 1977.

Reproduced with the permission of the copyright holder from Leepson, Marc. Consumer Protection : Gains and Setbacks. (Washington, Congressional Quarterly) 1978. p. 123–140. (Editorial Research Reports, 1978, v. 1, no. 7)

Another positive sign is the growth of consumer offices in state and local governments throughout the country. According to the Office of Consumer Affairs of the Department of Health, Education and Welfare, at least one office or division dealing with consumer affairs has been set up in each of the 50 states, the District of Columbia, Guam, Puerto Rico and the Virgin Islands. The total is 141.[2] The number of county consumer offices has grown markedly in the last few years—from only 18 six years ago to 150 today. City consumer departments have grown from 53 in 1971 to 67 today. *The Christian Science Monitor* reported recently that "more than 600" local, county and state government consumer protection agencies are in operation—"a figure that has doubled in the past two years."[3]

New Jersey has one of the most comprehensive state consumer programs. The New Jersey Division of Consumer Affairs works with some 100 county and municipal consumer offices throughout the state. This Consumer Affairs Local Assistance Network handles consumer complaints, corrects frauds and conducts educational programs. In May 1974, the state created the nation's first Cabinet-level Department of Public Advocate with wide powers to sue in the public interest. The Public Advocate office has rolled back rent increases in state-run housing units and helped get voting rights for mentally retarded persons in state institutions.

Among the most successful of the newer county consumer programs is the Los Angeles County Department of Consumer Affairs, which started operations in April 1976. The agency has received some 80,000 telephone inquiries since that time, and has investigated some 10,000 consumer complaints. Many cities across the nation—including Chicago, Honolulu, Boston, Detroit, Atlanta, Houston and Columbus, Ohio—have complaint centers to hear consumer grievances about city services. Local consumer agencies are "gaining more authority all the time," *Business Week* magazine commented recently, "and the scope of consumerist activities at the state and county levels is growing accordingly."[4]

Public Perception of Consumer Movement

Consumer affairs offices exist in all Cabinet-level departments of the federal government, as well as in most independent agencies, from the Civil Aeronautics Board to the Small Business Administration. In addition, the government operates the Federal Information Center which provides citizens with information about the government and helps with specific consumer problems. Located in major cities across the country, the offices are run by the General Services Administration and the Civil Service Commission.

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[2] Office of Consumer Affairs, U.S. Department of Health, Education and Welfare, "Directory of Federal, State & Local Government Consumer Offices," Aug. 1, 1977, p. 8.

[3] *The Christian Science Monitor*, Jan. 27, 1978.

[4] "Local Muscle for Consumers," *Business Week*, Sept. 26, 1977, p. 146.

There are other, less tangible, signs of the consumer movement's imprint on American life. A national opinion survey conducted by Louis Harris and Associates for Sentry Insurance indicated that most Americans believe the consumer movement has significantly improved conditions in the marketplace in the last 10 years. Seventy-two per cent of those polled in the February 1977 survey said they believed their shopping skills had improved in the last 10 years; 70 per cent felt that labeling and product information had gotten better; and 60 per cent believed that the safety of most products had improved.

The study also indicated a large measure of distrust of business. Exactly half of those questioned said that consumers do not get a better deal in the marketplace than they did 10 years ago; 61 per cent believed the quality of most products and services has grown worse in the last decade. The main consumer concerns were the high price of products, the high cost of medical and hospital care, the poor quality of products, and the failure of many products to live up to advertised claims. The survey concluded: "In the next few years [the business community] can expect to be vigorously attacked by both consumer activists and elected representatives. And it will be more severely regulated unless there are major changes within the business world."[5]

Recent Defeat of Consumer Agency Bill

There have been other gains in the consumer movement in recent years. Increasing numbers of federal, state and local consumer protection laws and regulations have been implemented. Budgets and working capital for consumer groups—both private and governmental—have generally risen, as has the number of persons actively working in consumer groups. Many newspapers and television and radio stations have hired consumer affairs experts. And some businesses have taken voluntary steps to help consumers. Many grocery stores provide open-dating of perishable products.[6] Some give comparative prices for different sizes and brands of the same items. Some food processors exceed government requirements for ingredient and nutritional labeling. Other manufacturers offer expanded guarantees and warranties.

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[5] "Consumerism at the Crossroads," Louis Harris Research Study, May 1977, pp. 6-7.

[6] Open-dating means that the date by which a product should be sold to ensure freshness is clearly marked on its container.

In spite of these positive signs, the consumer movement has faced some setbacks in the last several years. By far the biggest disappointment has been Congress's unwillingness to enact legislation creating a consumer protection agency. Legislation to establish such an agency was introduced for the first time eight years ago.[7] In spite of a heavy lobbying effort by consumer groups, the House of Representatives Feb. 8 rejected creation of a federal consumer protection agency by a 227-189 vote. The vote came on a considerably scaled-down version of previous consumer agency bills. The legislation nevertheless would have given the agency power to represent consumers in government proceedings. Observers believe that the House vote reflected congressional unhappiness with setting up yet another federal agency as much as it did anti-consumer sentiment.

Some laws passed by Congress in recent years have had unintended effects that have hurt the consumer cause. Several of them, in the words of Arthur E. Rowse, "have boomeranged or failed to come close to original expectations." The Truth in Lending Act of 1968 is one example. It was intended to give consumers useful information about loan and credit charges. But some businesses that had not imposed credit charges took advantage of the law's complicated and ambiguous wording and began to do so. Others increased credit charges. The Senate Banking Committee recently began considering ways to simplify the law.

Another law that has not worked as intended is the 1974 Employee Retirement Income Security Act. Marjorie Boyd has called the act, which was designed to simplify private pension plans, "perhaps the most complicated piece of regulatory legislation ever devised."[8] In order to comply with the law, some small businesses have been forced to make costly investments to set up employee pension plans. Boyd wrote that within two years after the measure became law, some 10,000 companies dropped their pension plans rather than comply with the law's complicated provisions.

The 1975 Magnuson-Moss Warranty Act[9] is another case in point. The measure gave the Federal Trade Commission power to set standards for written warranties on products priced at more than five dollars. The law's vague language, some claim, allowed furniture and appliance manufacturers to stop issuing some warranties and weaken existing ones. Other consumer-oriented rulings have proved unpopular with the public and, according to Chuck Fager, they "have produced, or have been manipulated to produce, widespread skepticism about the federal government's capacity to write effective consumer legislation in many areas."[10]

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[7] The Senate passed a bill in 1970 but it was blocked in the House Rules Committee. The House passed a bill in 1971, but the Senate version was killed by a filibuster in 1972. Consumer protection agency bills were nearly enacted in the 93rd (1973-74) and 94th Congresses, but the opposition of Republican administrations and business groups proved too powerful. See Congressional Quarterly's *Congress and the Nation*, Vol. IV, p. 434.

[8] Marjorie Boyd, "The Protection Consumers Don't Want," *The Washington Monthly*, September 1977, p. 30.

[9] Named for Sen. Warren G. Magnuson (D Wash.) and Rep. John E. Moss (D Calif.).

A Department of Transportation regulation requiring auto manufacturers to install interlock systems that prevented cars from being started until seatbelts were fastened was widely criticized. Congress passed legislation in 1974 overruling the department's order. The bill stipulated that the interlock system would no longer be mandatory and that existing systems could be legally dismantled. The Food and Drug Administration proposed a ban on saccharin, the only artificial sweetener available in the United States, in March 1977. The announcement drew angry protests from consumers and representatives of the food industry. The FDA ban was based in part on Canadian tests that showed rats fed high dosages of saccharin developed bladder cancer. In November 1977, Congress voted to delay the ban 18 months until further tests were completed by the National Academy of Sciences.

Criticism of Product Safety Commission

Consumer unhappiness with government-run programs can perhaps best be illustrated by examining the Consumer Product Safety Commission, an independent agency set up by Congress in 1972. The agency is headed by a five-member commission and has the authority to set safety standards for consumer products and to ban products presenting an unreasonable risk of injury. When the commission was established in 1972, it received widespread support from consumer groups.

Since then, the agency has come under wide-ranging criticism. Its chairman, S. John Byington, submitted his resignation Feb. 8 in the face of complaints that the commission does not act quickly or efficiently.[11] Howie Kurtz, a Washington, D.C., investigative reporter, wrote recently that the commission has "been such an abysmal failure that it is at least as responsible as any other government agency for the plummeting popularity of consumer protection."[12] Jo Thomas of *The New York Times* wrote that the commission "is almost universally regarded as feeble, tardy and reluctant in banning or recalling dangerous products and in setting Federal safety standards."[13]

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[10] Writing in the newsweekly, *The Boston Phoenix*, Jan. 10, 1978, p. 7.

[11] Byington will leave office June 30, 1978, four months before his term expires.

[12] Howie Kurtz, "The Consumer Product Safety Commission and Asbestos," *The Washington Monthly*, December 1977, p. 29.

[13] *The New York Times*, Jan. 30, 1978.

Strong indictments of the Consumer Product Safety Commission also have come from government investigatory units. A General Accounting Office (GAO) report[14] took the commission to task for not developing and issuing safety standards promptly. During its first four years, the commission issued standards for only three products—swimming pool slides, architectural glass and matchbooks. The GAO report said that the commission took an average of 834 days to develop those standards, far more than the 350 days Congress specified in the 1972 legislation setting up the agency.

A report by the U.S. Civil Service Commission[15] also was highly critical of the consumer commission. The report found that it "violated personnel laws, regulations and requirements" in 30 cases by giving preferential treatment and personal favoritism to hired consultants. The report blamed Commission Chairman Byington and his former top administrative aide, Albert Dimcoff, for the violations.

A third highly critical report was made public Feb. 1, 1978, in *The Washington Post.* The newspaper reported that a 170-page internal commission report said that the commission had been ineffective in performing its main function—reducing product-related injuries to consumers. "Overall, consumer product-related injuries requiring emergency medical treatment have increased by 44 per cent in the CPSC's five-year history," the report stated. Several factors were cited for the commission's poor performance, including "political or leadership disagreements among the commissioners...tensions between staff and commissioners...staff performance...[and] the effects of having no permanent Executive Director for so long." The report did praise some of the commission's work, especially the development of toy safety and crib construction standards.

Consumer Product Safety Commission officials have defended the agency. Byington said recently that "the critics overlook the fact that the very existence of the agency has been a positive factor in terms of improved safety. There have been dramatic improvements in the whole area of outdoor power equipment.... The standards adopted by the industries have been tightened substantially. Toys are another area where the industry itself has made dramatic improvements."[16]

Two rulings by the commission have been particularly unpopular. The first, in 1972, required that children's sleeping garments be treated with flame-retardants. Then, in 1977, the agency banned use of one of the chemical retardants, Tris, after determining that it could cause cancer. The two actions angered both manufacturers and consumers. Parents faced higher prices for children's sleepwear in 1972 when the chemical flame retardants were added. Manufacturers protested the ruling that allowed purchasers of Tris-treated garments to have their money refunded. Sleepwear producers say the costs of developing new flame retardants will mean even higher prices.

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[14] "The Consumer Product Safety Commission Needs to Issue Safety Standards Faster," Dec. 12, 1977.

[15] "Merit System Investigation in the Consumer Product Safety Commission Headquarters, Washington, D.C.," Jan. 12, 1978.

[16] Interview published in *U.S. News & World Report*, Oct. 24, 1977, p. 34.

The commission also has been criticized for not moving quickly against asbestos, which some tests indicate can cause cancer. The agency recently issued a ban on the asbestos coating on artificial fireplace logs. But it took two years to do so. Asbestos is an ingredient in many other products, including children's modeling clay and papier maché. Some time this year the agency is scheduled to issue safety standards for power lawn mowers. gas space heaters, Christmas lights, contact adhesives, communications antennae and baby rattles. The agency also plans to hold regional hearings to let consumers around the country have some voice in influencing rulemaking. But criticism continues and the Consumer Subcommittee of the Senate Commerce, Science and Transportation Committee will be looking into the agency's operations in hearings scheduled for Feb. 24 and 27.

Activities of Nader Groups

CONSUMER CONSCIOUSNESS is due in large part to the activities of Ralph Nader, a 43-year-old lawyer who was virtually unknown to the public only 12 years ago. "If I were to do a social history of the 1960s and 1970s, I'd write it in terms of Ralph Nader," Carol Tucker Foreman, Assistant Secretary for Food and Consumer Services at the U.S. Department of Agriculture and former head of the Consumer Federation of America, said recently. "He influenced more people than anyone else."[17]

David Ignatius, who worked as a Nader lobbyist in 1973, has written that Nader's career can be divided into four stages. A look at these stages reveals some of the successes and failures of the U.S. consumer movement since the mid-1960s. Nader's career as the nation's foremost consumer advocate began in November 1965 with publication of his book *Unsafe at Any Speed: The Designed-in Dangers of the American Automobile.*

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[17] Quoted in *The Washington Star*, Jan. 1, 1977.

Although he attacked the whole Detroit automobile industry for emphasis on profits and styling over safety, Nader concentrated his fire on the Chevrolet Corvair, "one of the nastiest-handling cars ever built." The book became a best-seller, and the demise of the Corvair was attributed to its influence.

Meanwhile, congressional support was growing for passage of auto-safety legislation, and Nader testified on behalf of such a bill early in 1966. On March 6, 1966, newspapers published Nader's complaint that he had been under investigation by private detectives hired by the auto industry. Three days later, General Motors conceded that it had initiated a "routine investigation" of Nader to find out if he had any connection with damage suits that had been filed against the company because of defects in the Corvair.

In a nationally televised hearing on March 22, GM President James M. Roche told the Senate Subcommittee on Executive Reorganization that there had been "some harassment," and publicly apologized to Nader. Final passage of the National Traffic and Motor Vehicle Safety Act of 1966 came five months later. After the General Motors apology, Ignatius wrote: "The Nader legend was born. An aroused citizen had waged a successful guerrilla campaign against the world's most powerful corporation."[18]

The second phase of Nader's career lasted from 1968 to 1970. An organizational period, it featured the opening of the parent Nader organization, the Center for the Study of Responsive Law, in June 1969. The center is a Washington-based tax-exempt organization. It operates on a yearly budget of some $300,000, much of it provided by foundations. The center is perhaps best known as a staging area for the activities of "Nader's Raiders"—groups of young people who gather in Washington during the summer months to ferret out information from government and business groups for subsequent reports.

The Center for the Study of Responsive Law has produced reports on the Federal Trade Commission, the Interstate Commerce Commission, the Food and Drug Administration and on antitrust enforcement, occupational safety and health laws, air pollution, airline safety, nursing homes and the medical profession—among others. The exposés of waste and inefficiency that some of the reports documented won Nader and his raiders the title of modern-day muckrakers. The successes of Nader's organization helped the consumer movement in general to grow rapidly.

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[18] David Ignatius, "Stages of Nader," *The New York Times Magazine*, Jan. 18, 1976, p. 9.

Nader and Congress

Ralph Nader has never been shy about criticizing those who he believes act contrary to the interest of American consumers. When the proposed consumer protection agency bill failed in Congress last year, Nader spoke out harshly against some liberal House members for their lukewarm support.

This year for the first time Nader's major lobbying organization, Congress Watch, will be working in congressional districts throughout the country during the 1978 House campaigns. Congress Watch Director Mark Green said recently that the local groups "will be a way to get information on to people...about what their representatives are really doing, as opposed to what they may say they're doing and to mobilize public support for our issues.... We're still thinking about whether to make formal endorsements; we might."

Nader summed up his position on politics in this way: "Liberal *versus* conservative is no longer the real dividing line in politics; the actual distinction is between the 'corporatists,' those who support and expand the power of corporations, and 'consumerists,' those who are working to expand the power of the people. The abuse of power by large corporations is the number-one issue in our society and we intend to make it the major political issue in 1978."

During the third phase of his career (1970-1972) Nader began the push for federal legislation setting up a consumer protection agency. Congress's unwillingness to do so, after months of intense lobbying by the Nader organization, led to a second major Nader undertaking: the formation in November 1971 of a 1,000-member team to conduct a yearlong study of Congress. The authors of the Congress Project set out to rate each member of Congress running for re-election in 1972. Nader characterized the effort as "the largest study of [Congress] ever conducted—an effort to share with citizens a better understanding of how the members and committees of our national legislature operate both among themselves and in relation to outside forces working on the Congress."[19]

"Everyone who had anything to do with it—Ralph Nader included—now admits the Congress Project was something of a boondoggle," Ignatius, who himself helped with some of the profiles, wrote. The main problems were the large volume of work and the short time to complete it. All the work was scheduled to be released before the November 1972 elections and the massive effort to complete the project was further hampered by administrative and organizational problems.

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[19] Ralph Nader and Robert Fellmeth, writing in the introduction that accompanied the profiles, "Ralph Nader Congress Project, Citizens Look at Congress," August 1972.

Little new information was contained in the profiles. There were no sensational revelations or charges. *The New York Times* commented [20] that the profiles were "unlikely to furnish any damaging information that could not have been obtained elsewhere with a little digging."

The other significant undertaking during the "third phase" of Nader's career was the establishment of the Public Interest Research Group (PIRG) in 1970. The PIRG, which has been described as Nader's public-interest law firm, has satellite organizations on 145 college and university campuses with some 500,000 student members. Aside from student fees at the various colleges, the organization's budget is met by Nader's lecture fees and book royalties. Nader also donated the proceeds from an out-of-court settlement on an invasion-of-privacy suit against General Motors—estimated at some $270,000 after taxes and attorney fees.

Litigation, Lobbying and Organizing

The fourth phase of Nader's career began in 1972 and lasted into 1976. Ignatius described the period as one in which Nader embraced "the traditional tools of interest-group representation: litigation, lobbying and grass-roots organizing." Nader succeeded in setting up a relatively smooth bureaucracy, Ignatius wrote, "with a sensible delegation of authority, leaving him free to ruminate on the future."

In 1972, Nader established the tax-exempt Public Citizen, an umbrella-group, which directly supports four other Nader organizations: (1) the Citizen Action Group, which includes the Public Interest Research Group; (2) Congress Watch, a full-time lobbying office with a yearly operating budget of $145,000 and seven full-time lobbyists, which succeeded the Congress Project; (3) the Public Citizen Litigation Group, set up with a staff of eight attorneys to act in legal suits for consumers, especially in Freedom of Information suits; and (4) the Health Research Group, which studies and researches health issues.

Headed by Dr. Sidney Wolfe, the Health Research Group has petitioned the Food and Drug Administration to act against certain drug manufacturers and it was successful in helping ban the artificial food coloring, red dye No. 2. The Health Research Group conducts policy-oriented research on such issues as unnecessary surgery, comprehensive health planning, hospital construction and operation, mental illness, nutrition, drugs, pesticides and carcinogens, dental health and the education and training of health professionals.

Since 1976, articles in national news magazines and major newspapers have examined Nader's career and questioned his effectiveness and power and that of the entire consumer movement. The debate over Nader's effectiveness was sparked by the 1976 publication of the book *Me & Ralph: Is Nader Unsafe for America?* by David Sanford, then managing editor of *The New Republic*. In his self-described "rare and controversial view" of Nader,[21] Sanford conceded that Nader had done an admirable job working for American consumers, especially in influencing Congress to pass important consumer legislation. But the book concentrated on Nader's personal life—his personality, living habits and financial affairs. Sanford presented an overwhelmingly negative picture of Nader, accusing him of acting in his own self-interest rather than for consumers.

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[20] Oct. 22, 1972.

Some Nader supporters said the book was part of a personal vendetta against Nader. Theodore Jacobs, a Nader aide, wrote that Sanford's "allegations about...Nader are based on double and triple hearsay and consequently suffer from inaccuracies and misrepresentations."[22] Mark Green, the director of the Congress Watch project and a long-time Nader associate, called it a "pastiche of gossip, innuendo and error about Ralph Nader." Nader himself termed the book "a dirty trick." "One of the things that was so irritating," Nader said, "was his [Sanford's] faking a close association with us. I've talked to him less than three hours in the last nine years."[23]

Debate Over Nader's Influence and Power

Questions about Nader's effectiveness and speculation that he had lost influence and power continued through 1977. Two incidents fueled the controversy. The first was the largely negative reaction by political commentators and sports columnists to the formation of FANS—the Nader-sponsored Fight to Advance the Nation's Sports. The purpose of the group, Nader wrote,[24] was to allow sports fans to "exercise some fundamental consumer rights to know and to shape the product or service they are buying." Among the issues to be confronted were the high and growing cost of tickets, the high-priced, low-nutrition junk food sold at sports arenas and television blackouts. Nader said FANS eventually would focus on bigger issues, such as excesses by sports corporations and the over-extension and overlap of schedules of different sports.

"The owners and the players each have their own protection organizations. It's time the fans have one of their own," Nader said as he and lawyer Peter Gruenstein announced the formation of the organization Sept. 27, 1977, in Washington. An editorial in *The Washington Post* Sept. 29 criticized FANS' formation, saying that Nader was overextending himself: "The idea that organizations can speak for groups of people is getting out of hand.... [B]eing a sports fan, after all, is a little different from being a food buyer—or a taxpayer. You don't have to be one if you don't want to."

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[21] David Sanford, *Me & Ralph* (1976), p. xii. Sanford currently is managing editor of *Skeptic* magazine.

[22] Writing in the letters column of *The Washington Post*, Aug. 11, 1976, in response to a letter Sanford wrote about the book.

[23] Quoted in *The Washington Star*, Jan. 1, 1977.

[24] In his nationally syndicated column, published June 11, 1977, in *The Washington Star*.

Newspaper columnist George F. Will also attacked the organization. "FANS is like many organizations that are concocted by 'consumerists' skillful at making work for themselves," Will wrote. "It is the assertion, by a few persons who have appointed themselves to speak for many strangers, of concerns that few consumers share...."[25] Television commentator Eric Sevareid chided Nader for concerning himself with food at ballparks. Sevareid said Nader "would drive out the odor of peanuts and popcorn from ballpark and football stadium and spray the joints with astringent fumes of the germicide called Social Responsibility."[26]

The controversy over FANS is not crucial in terms of assessing the strength of the entire American consumer movement. But the reaction to its founding illustrates that Ralph Nader—who for much of his career had been extremely popular and rarely criticized except by conservative supporters of big business—can no longer count on general public acceptance of his every move.

Another round of anti-Nader criticism followed soon afterward. The uproar came after Nader publicly upbraided Joan Claybrook, head of the National Highway Traffic Safety Administration, who had been one of Nader's closest associates when she served as his chief congressional lobbyist.[27] Nader charged that Claybrook had "etched a trail of averted or broken promises" and demanded her resignation in a long letter made public early in December 1977. He accused her of betraying consumers by supporting a Carter administration decision to give auto manufacturers six more years to install air bags in cars.

Nader's outburst drew wide attention. Ross K. Baker, a professor of political science at Rutgers University, wrote that Nader's attack on Claybrook and other outbursts at government officials was symptomatic of Nader's unwillingness to realize that the federal government must be responsive to all interests—not just to consumers. "Having succeeded to a remarkable degree in placing people identified with consumerism and public-interest activity in the Carter Administration," Baker wrote, "the zealots on the outside are attacking and repudiating their erstwhile colleagues for their moderation in the pursuit of reformist objectives."[28]

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[25] Writing in *The Washington Post*, Oct. 2, 1977.

[26] Quoted in *The Wall Street Journal*, Dec. 13, 1977.

[27] Former Congress Watch lobbyist Nancy Chasen described Claybrook in 1976 as "undoubtedly [Nader's] most trusted employee—more so than anybody. She has extremely direct access to him. There is no issue that she is left out of." Quoted in Sanford, *op. cit.*, p. 80.

Has Nader's overall impact been significantly reduced by the Sanford incident, the creation of FANS and the Claybrook attack? Nader denies that he has lost any power. "There are two ways you can judge it," Nader said recently. "First, consider who we are up against. If we can come up neck and neck against the biggest coordinated lobby of trade groups ever, as we did on the consumer protection agency bill last fall, that's real power.... Second, you judge by whether a group wins its battles, and achieves what it's aiming at; or if you lose, by how close you come. And in those terms we've also been doing well."[29]

Rep. Toby Moffett (D Conn.), one of the leading voices for consumers in Congress, said recently that although Nader himself may be losing some influence, his lobbyists are becoming more effective. What Nader is doing, Moffett said, "is creating what I call an information stalemate. Ten years ago, you had information pouring in from the special interests but nothing to counter it. What Nader has done is even up the odds on information...."[30] While there may be disagreement on whether Nader himself has lost power and influence, there can be no doubt—as Moffett indicated—that the Nader organization is an established, effective voice for consumer causes.

Future of American Consumerism

PRESIDENT CARTER came to office last year with wide support from the nation's consumer leaders. Ralph Nader described Carter's views on consumer issues as "a breath of fresh air" compared to those of Presidents Nixon and Ford. Nader met with Carter Aug. 7, 1976, and pronounced Carter's positions on consumer issues "better than [those of] any candidate that has achieved the nomination of any major party in recent decades."[31] Speaking at a Nader-sponsored Public Citizen Forum in Washington, D.C., two days later, Carter said he wanted to challenge Nader "for the title of top consumer advocate in the country." Other national consumer leaders, including Kathleen O'Reilly, executive director of the Consumer Federation of America, also praised Carter's positions on consumer issues, especially his support for the proposed consumer protection agency and class action lawsuits by citizens. A group called Consumers for Carter, which included Bess Myerson, former New York City consumer affairs commissioner, formed to help the Carter presidential effort.

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[28] Writing in *The New York Times*, Dec. 8, 1977.

[29] Quoted in *The Boston Phoenix*, Jan. 10, 1978, p. 7.

[30] Quoted in *National Journal*, Dec. 31, 1977, p. 1995.

[31] Quoted in *The Washington Post*, Aug. 8, 1976.

After the election, Nader's support for Carter faded somewhat. Nader found fault with Carter's initial Cabinet appointments, especially Energy Secretary James Schlesinger, and Treasury Secretary W. Michael Blumenthal. Nader accused Schlesinger of favoring nuclear energy at the expense of solar energy and conservation. Blumenthal, Nader told reporters, is not "someone who has had a record of strong commitment...to using the Treasury Department as something other than a plantation for bankers, trying to get genuine tax reform and trying to use the leverage of monetary policy and the Treasury's resources for housing and other purposes."[32] Nader did praise some of Carter's appointments, including Secretary of Labor F. Ray Marshall, Secretary of Health, Education and Welfare Joseph A. Califano Jr. and Secretary of Agriculture Bob Bergland.

Public Interest Activists in Government

Generally, there has been high praise from other consumer leaders for the large number of appointees with consumer backgrounds in the Carter administration. Important positions have gone to former public-interest lawyers, consumer advocates, civil-rights workers and environmental activists. Juan Cameron reported that some 60 former public interest advocates hold important positions in the federal government.[33]

One of the former consumer advocates in the Carter administration is Peter Schuck, HEW's Deputy Assistant Secretary for Planning and Evaluation, who previously served as Washington director of Consumers Union *(see p. 139)*. Schuck said recently that he, like many others newly appointed to government positions, faced problems with the vast size and procedural difficulties within the government bureaucracy. "It's a very stimulating experience, but it has also confirmed my worst suspicions about how difficult it is to get things done in a bureaucracy," Schuck said recently. "There are just so many bases to touch, so many groups to be conciliated."[34]

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[32] Interviewed on "Face the Nation," (CBS-TV), Dec. 26, 1976.

[33] Juan Cameron, "Nader's Invaders are Inside the Gate," *Fortune*, October 1977, p. 252.

[34] Quoted in *Newsweek*, Jan. 12, 1978, p. 22.

Robert Greenstein, a former lobbyist for the Community Nutrition Institute, now is a special assistant to Agriculture Secretary Bergland. As a public-interest advocate, Greenstein worked to liberalize food stamp laws. He was assigned the same task when he entered government. "I never dreamed I would get involved in this, much less be one of the principal advisers on the new [food stamp] legislation," Greenstein said last fall.[35] He is credited with writing an important change in the new food stamp law that allows qualified recipients to receive stamps without paying for them.

Changes at the Federal Trade Commission

The former consumer advocate with perhaps the most potential to influence the marketplace is Michael Pertschuk, chairman of the Federal Trade Commission. As chief of staff of the Senate Commerce Committee, Pertschuk earned a reputation as a campaigner against unfair business practices and for consumer rights. Pertschuk has promised to make the FTC, which enforces the antitrust laws either through voluntary compliance or court action, a voice for consumers. "We want to make sure consumers are better off than they were before as a result of our actions," Pertschuk said recently.[36]

Pertschuk took over as FTC chairman in May 1977. He has instituted several changes since then. The commission now allocates funds to consumer group representatives to attend FTC rule-making hearings, something the groups had not been able to afford to do in the past. Pertschuk has overseen a general reorganization of FTC procedures aimed at enabling the commission to move quickly to obtain injunctions and get penalties by direct court action.

Pertschuk has been criticized by both business and consumer representatives. Consumer groups say the commission has not moved quickly enough under Pertschuk and that the commission has not significantly aided the consumer cause since he took over in May 1977. On the other hand, businesses generally do not like his pro-consumer outlook. "We are not happy with him," Barry A. Friedman of the U.S. Chamber of Commerce said recently. "He's taken a strong pro-consumer position..." that potentially could harm business.[37]

The future of the American consumer movement hinges on many factors. The pivotal question, Arthur E. Rowse of *Consumer Newsweekly* wrote recently, is whether organized consumers can "ever build up enough power to forge significant improvements in the marketplace and society." One measure of the consumer movement's strength is the fate of the Consumer Protection Agency Bill. Many agree with the assessment of Rep. Benjamin S. Rosenthal's (D N.Y.), "I think we have heard the last of it, at least for a time," Rosenthal, a sponsor of the bill, said Feb. 9. "The margin of defeat was significant, and I don't see any basis for us to recover...."

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[35] Quoted by Juan Cameron, *op. cit.*, p. 253.

[36] Quoted in *The New York Times*, Jan. 19, 1978.

[37] Quoted in *The New York Times*, Jan. 19, 1978.

Size and Shapelessness of the Movement

One thing that contributed to the bill's failure is a probproblem that has plagued the American consumer movement from its beginnings 15 years ago—the movement's inability to present a totally united front on most issues. The consumer movement, almost by its definition, is as fragmented as the myriad needs the consuming American public has. The Nader organization, with 100 people working full-time in Washington on a yearly budget of some $1.1 million, is the closest thing to a national consumer organization. But the principal Nader organization, Public Citizen, is involved with many different issues and does not directly involve the public.

Lee Richardson, former president of the Consumer Federation of America and now head of HEW's Office of Consumer Affairs, said recently that ultimately "we may need a national membership organization. Without one, it is a little bit scary. Other interests such as labor and women have built up solid constituencies with chapters and affiliates across the country. We are a long way from the kind of organization consumers need."[38]

There are several national consumer groups, but none represent the constituency of which Richardson speaks. The National Consumers League, Common Cause, Consumers Union of the United States and the Consumer Federation of America are the principal national consumer groups. The largest one, the Consumers Union, has been active since 1936, publishes the magazine *Consumer Reports* and has some two million members.

There is no question that the consumer movement has had an important impact on the American marketplace in the last 15 years. While there is no unified national consumer organization, there is a large and growing number of federal, state and local consumer-oriented government offices. And the Carter administration has proven to be very responsive to consumer demands. These signs strongly indicate that today's consumer movement will remain an important voice for change for years, if not decades.

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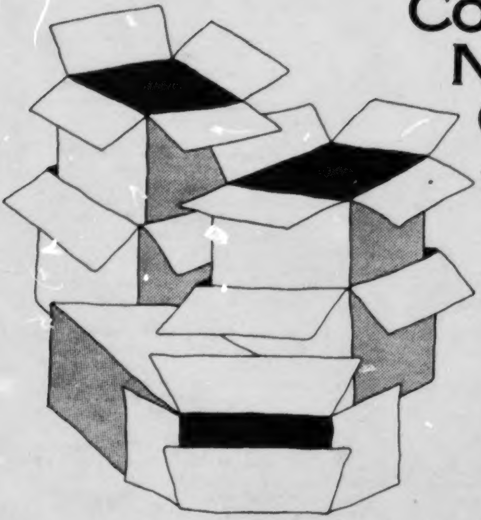
[38] Quoted in *The Washington Post*, Dec. 25, 1977.



The Consumer's New Concerns

by Sidney Margolius

Opponents of the consumer reform movement and even some friendly observers have seized on a recent slowdown in gains, including defeat of the consumer agency bill and diminished media interest, to proclaim that consumerism is dying out.

But those who think or hope so are wrong—because the nation has an underlying public demand for such reforms. They're needed to redress the personally and socially harmful injustices of the marketplace and stem the great waste of personal and national resources needed for other purposes.

In fact, all opinion surveys and other signs indicate that the public is far ahead of many government and business leaders in understanding the need for consumer protection.

Gallup polls the past two years found that most people considered the cost of living to be the nation's biggest problem. Several Harris polls found a majority of Americans favored the consumer agency Congress killed. Among other surveys, one by the Sentry Insurance Co. also found strong public feeling that consumer reforms are needed.

Further indicators of the public's consumer awareness are the many local groups that have sprung up around such specific issues as utility rates. And while Congress has seemed more resistant, state and local authorities have become increasingly active on behalf of consumers.

The public's consumer concerns are noticeably high in this year of record-high food prices and overall living costs. Moderate-income families are especially frightened by sudden sharp increases in food prices. They worry that a time may come when they may not be able to feed their families adequately on the money they have to spend.

So rather than consumerism dying out, as some would believe, we may need to be prepared for new interest at the local levels. This is where the real consumer movement is, and while it often seems leaderless and merely grumbling rather than articulate, it

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often responds to serious inflationary pressures with serious activity such as picket lines and pressures on Congress.

Trade union leaders have a special stake in effective consumer reforms because explosive price runups hit wage earners particularly hard and can quickly erase hard-won wage gains and abruptly erode already skimpy living standards.

From 1972 to June 1978, non-agricultural workers had what seems like a handsome rise in their gross average weekly earnings, from $136.16 to $205.46. But real buying power in terms of spendable, constant 1967 dollars actually fell over $3 in that time—from $96.64 to $93.21.

Financially-inexperienced workers have been manipulated and coerced into serious financial losses by rigged credit laws and powerful modern selling pressures and often into garnishment and sometimes even loss of jobs and homes.

But if consumerism is far from dead, it is true that the representation of consumers has narrowed somewhat and the choice of barricades has not always been the most central.

So many issues recently have been raised in the name of consumerism that the limited resources of the consumer movement are noticeably strained, and the attention of the public and public officials has become diffused. New professional consumer advocates and specialized consumer organizations have sprung up and gone off in many directions—sometimes with little or no first-hand background on particular issues. Young lawyers and others with little economic background have acted as consumer spokesmen on complex matters of meat grading, nutrition, vitamins, health foods, food costs, agricultural policy or life and auto insurance.

Sometimes because of the lack of experience of the new spokesmen or the time to sift through conflicting arguments, a few activists have been able to represent their personal views as those of many organizations.

A few of the hundreds of issues raised as consumer needs really are fostered by insurance, vitamin, health food or other commercial interests. They can sometimes mislead the inexperienced consumer activists who are themselves burdened with too many issues. Some other issues may be only dimly related to primary consumer problems or may be largely political. While most of the issues raised do have importance to consumers, there is a noticeable lack of priorities and a diversion from what may be the most urgent needs.

Earlier, and during the period of greatest gains, the main representation of the consumer had been by community organizations like unions, co-ops, women's organizations, settlement houses, credit unions, educators, housing co-ops, anti-poverty councils, church and senior groups, etc., and by spontaneous local groups that sprang up to meet specific crises like jumping utility or food prices.

These organizations have deep grassroots and ordinary people who had been victimized were brought forth in an effective drive to secure truth in lending, garnishment control, better drug regulation and other needed protection. Unions and some of the other community groups also were establishing group drug buying and optical services even before the 1959 hearings by Sen. Estes Kefauver focused attention on high drug prices.

The community organizations were also more effective because they have their own financial bases and were less hampered by the need to raise funds. In contrast, the new professional consumerists increasingly have sought grants from various government agencies. And some of the newer groups have expired, especially since Consumers Union has had to curtail its grants to such organizations because of its own financial problems.

The question of the possible effect on government grants on the independence of the consumer organizations has been raised. Perhaps of more concern is that some of the voluntary consumer organizations have turned to business organizations for funds to attend the many conferences that now take place and for other organization purposes. For example, phone companies, utilities and house-to-house sales associations have provided funds for such purposes for consumer groups or their representatives in recent years.

Officials of several Washington-based consumer organizations also have accepted fees for consulting with the American Council of Life Insurance, the largest insurance trade association. Such support has not been concealed, though it is not always widely publicized, and this writer has no evidence that it has influenced any of the organizations or individuals involved.

Competing interests and conflicts among some of the new professional consumerists also have attracted attention. Unions have no interest in the politics of the consumer movement. Their interest is simply to help workers get fair value for their dollars, and have reasonable protection in the marketplace from manipulation, deception, and product hazard.

But to approach that goal there is a need to maintain and even expand their interest and representation of consumers and not leave this area primarily to the new professional consumerists.

The defeat of the consumer agency bill affirms the need for a mass base and people-organizing and communication skills. Some of the activists assumed a threatening posture against reluctant Representatives, which only made the latter dig in even harder. Meanwhile the general public never did get a real understanding of the real purpose and need for the bill, and small businessmen were unnecessarily frightened.

It should be realized that the business of influencing the government has become Washington's second-largest industry, as Lee Richardson, acting director of the U.S. Office of Consumer Affairs, has pointed out. Today, some 3,000 corporations have offices in Washington compared with about 50 only 15 years ago. The area also now is headquarters for about 1,600 trade association, 13,000 lawyers and numerous consulting firms, all involved to some extent in the work of influencing the government, Richardson observes.

What are the consumer's main needs? The problems are many, especially in a deceptively affluent society marked by mass production methods but a wasteful, complicated marketing system. But there have been useful gains as well as setbacks.

Modern consumer problems began to proliferate right after World War II. Congress removed wartime price controls prematurely and set in motion a long inflation that fast-idled from time to time but never really stopped. Consumers also suffered quick defeats —such as the removal by Congress of the wartime requirements for labels on canned foods.

The proliferation of merchandise itself during the 1950s brought such problems as undependable quality, excessive prices, undependable guarantees, product safety hazards, duplication, the hard sell of TV, the use of easy credit and obsolete credit laws as levers of coercion, home improvement deceptions, referrals plans, domination of government agencies by their client industries, and the like.

The real period of consumer redress began about 1962 when the Kefauver drug amendments were passed and President John F. Kennedy appointed the first consumer council. The major gains were achieved during the 1960s and early 1970s when truth in lending, truth in packaging, auto and product safety and other landmark legislation was enacted, and government agencies such as the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) also moved to provide more consumer protection.

During this period other consumer legislation included cigarette labeling, controls on interstate land sales as well as closer regulation by the states, and expansion of meat and poultry inspection.

Perhaps the greatest gains were made in the area of greatest previous exploitation—consumer credit. Progress also has been made on the state level, both in supplementing and sometimes pioneering in various reforms. Some 40 states and many cities and counties now have consumer protection agencies or consumer divisions in their attorney general's office.

Despite the growing diffuseness of consumer representation, further gains have been made even in the most recent years—though a number look more like fringe benefits than some of the major advances of the 1960s and early 1970s. The recent gains include new regulations at federal and state levels to further strengthen the defenses of credit buyers; a reinforcing of the right of consumers to know beforehand the prices of some of the services they must buy, such as prescription medicines, eyeglasses and funerals; the providing of more information for buyers on energy consumption of cars and appliances; and the quest, still not wholly successfully, to relieve some of the disputes over warranty service by requiring more

clarity and an opportunity to read the warranty in advance.

Even after rejecting the consumer agency bill, Congress enacted the consumer co-op bank bill which had broad support of national organizations, including labor. Nor has the administration given up on expanding consumer representation in government. Esther Peterson, the President's consumer assistant, has announced a program to enlarge the scope of the present consumer office and of consumer representation in government agencies.

As in the earlier reform years, the greatest recent advances have been made in redressing damaging credit practices. Among the advances:

Holder in Due Course: Traditionally a finance company which took over an installment note from a dealer was considered an "innocent party" and as such relieved from making good on any defective or misrepresented purchases. The buyer simply had to keep on paying the finance company.

There was little problem in the case of scrupulous dealers. But some high-pressure sellers did shoddy or incomplete work or failed to make good on promises. With the installment notes now held by a third party, the aggrieved consumer sometimes had no place to turn.

As the result of changes in some state laws and recent FTC regulations, the subsequent holder of the installment note now is subject to all legal claims and defenses, which the debtor could assert against the original seller. Thus consumers who have reason to feel they were deceived now have the right to sue the finance company too.

Repossessions: Another help is the action by several states requiring finance companies to notify defaulting debtors of their legal rights to recover repossessed cars by paying only the past due installments and repossession costs and not the entire balance.

Door-to-Door Salesmen: Under FTC and many state regulations, if any item costing $25 or more is sold to a consumer at home or anywhere other than the place of business of the seller, the consumer has the right to cancel within three business days.

Collection Safeguards: A number of proceedings and regulations by both federal and various state authorities are operating to restrain abusive methods used by some bill collectors and about which local unions and members often have complained.

One much-criticized practice was the threat to contact a debtor's employer.

Equal Credit: This recently enacted law prohibits creditors from denying people credit because of sex, marital status, race, age, or receipt of public assistance benefits. Among other practices the law bars are several previously used to deny women access to credit on their own account.

Another important area has been recent efforts by federal and state agencies as well as businesses themselves to spur greater price competition.

These efforts, usually in the form of legal suits, have been aimed at both actual price fixing on a wide variety of industrial and consumer products, and the follow-the-leader type of price setting for which some industries have long been criticized.

In 1976, a price fixing device long resented by consumers was finally eliminated when Congress repealed the so-called "fair trade" laws in the 21 states which still had them. The state "fair trade" laws, enacted during the depression of the 1930s, permitted manufacturers to set the retail prices for their products even if some retailers were willing and able to charge less. The climate of the depression made it desirable to stop undercutting by firms for a temporary advantage, but that climate had long since passed before the "fair trade" laws were repealed.

Court decisions, rather than legislation, have produced some other useful advances. One, which opened up price advertising of professional services, was the 1976 ruling by the U.S. Supreme Court which removed laws in 34 states prohibiting pharmacists from advertising the prices of prescription drugs. Virginia unions joined with consumer groups to win this court suit.

The ruling was based on the First Amendment guarantee of free speech. Justice William H. Rehnquist, who cast the only dissenting vote in the 7-1 decision, argued that the ruling "cannot be limited merely to dissemination of price alone, and . . . cannot possibly be confined to pharmacists without likewise extending to lawyers, doctors and all other professions." It has already had that effect.

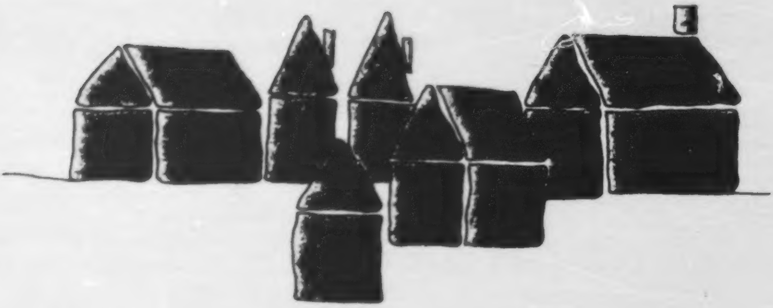
The consumer agenda—or shopping list of consumer needs begging for attention—remains long even after the advances of recent years.

Many of the consumer issues recently raised are useful. Some may be peripheral. Earlier consumer interests were mainly related to economics and product safety. Now have been added equal rights, the environment, overuse of chemicals in food, and sometimes special pleading, as by people connected to the health food industry.

The other most urgent needs might well include these largely economic areas:

- Housing costs are the most pressing problem and by far the largest item in the consumer budget. Unfortunately, some of the government's activities are inadequate. Absent from the Carter Administration's inflation plan was any proposal to reduce the present steep mortgage rates of 9 to 10 percent. Moreover, the Federal Reserve Board has continued on a tight-money, high-interest policy despite the recent change in leadership at the federal level.

Too, a number of federal agencies are playing the mortgage lenders' game by supporting such illusions



as variable mortgages and graduated payment plans. These schemes ultimately mean that home buyers would have to pay still higher costs.

- Food costs are another leading problem, especially since the new 1978 surge in prices. At present, 60-62 cents of the consumer's food dollar goes to those handling food between the farm and market—a "spread" that should be reduced.

Several of the Washington-based consumer organizations are making a valiant and useful effort to get the government to take steps to stimulate competition in the food industry. These efforts need support and additional expertise.

In an age of processed foods, consumers also have the right to more facts than they now get on ingredients. The FDA and the Department of Agriculture have said they are interested in requiring additional information on labels but are very slow to take any real action.

- Heavy installment buying and borrowing at high finance charges is a continuing problem. Already total consumer debts are over $240 billion. Such heavy use of credit often leads to serious overindebtedness and the now familiar train of garnishees, often followed by debt adjustment plans and bankruptcy. A big consumer debt load always is a recessionary threat.

But even among families who don't become seriously overindebted, constant payment of large finance charges on installment purchases frequently results in a habitual loss of perhaps 4 to 5 percent of a family's entire income.

- Inadequate health insurance compared to today's soaring medical and hospital fees, are a persistent dilemma along with the need to control such costs through better delivery of health services. Large medical bills also happen to be one of the leading causes of overindebtedness and sometimes bankruptcy.

- In an age of proliferating merchandise—sometimes of undependable quality that wastes the consumer's and the nation's resources—minimum-quality standards are a pressing, long-term need. Some beginning steps have been made in this direction, with government grades used on many foods (though improvements need to be made in the grades themselves); in the new grading system just announced for tires; in the few product safety standards so far developed; and in the new energy consumption labels required on cars and appliances.

- Auto insurance costs, and sometimes the difficulties in getting any coverage, are another troubling area for workers. No-fault auto insurance laws have failed to restrain rate increases in states which enacted them, and serious reforms of the industry and its marketing methods itself seem to be needed.

These are some of the main consumer needs which may require priority attention. But consumers and their allies also need to be aware of the need for improvement in some of the legislation already enacted.

The new warranty law is not helping much with some of the worst problems, like car warranties. As one of the original commissioners, I would judge the Consumer Product Safety Commission has been hampered by political appointments of people with little background in this area, as well as some who didn't even believe much in the need for the agency. So merely enacting legislation doesn't necessarily solve the consumer problem. The new legislation may need public as well as congressional oversight.

Too, some present legislation and existing government bodies can be more effective on the consumer's behalf—as the FTC recently demonstrated with its notable change in the holder-in-due-course doctrine.

While consumer redress is not simplistic and actually will never be fully completed, useful advances have been achieved. They can continue to be if community organizations help provide the mature leadership and the grassroots support as before.

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TOWARD A NEW CONSUMER PROTECTION

ROBERT B. REICH†

Consumer protection is everywhere in retreat. Congress has rejected the Food and Drug Administration's proposed ban on saccharin,[1] and several courts and state legislatures have attempted to block the FDA's attack on Laetrile.[2] The Consumer Product Safety Commission's recent ruling that swimming pool slides must carry danger warnings[3] has elicited widespread ridicule, brought a reversal in the federal courts,[4] and contributed to rumors that the Commission itself will be abolished. Congress has rescinded the

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[1] The rejection took the form of an 18-month moratorium on the FDA's authority to ban saccharin. Saccharin Study and Labeling Act, Pub. L. No. 95-203, § 3, 91 Stat. 1452 (1977) (codified at 21 U.S.C. § 348 (Supp. 1977)). The moratorium expired in mid-1979, and the House moved quickly to extend it until 1981. 125 CONG. REC. H6485 (daily ed. July 24, 1979).

[2] The decision of the United States Supreme Court in United States v. Rutherford, 99 S. Ct. 2470 (1979), rejected an attempt to defeat the FDA's efforts to regulate interstate distribution of Laetrile, but made no findings as to the drug's safety or effectiveness. While the *Rutherford* decision appears to clear the path for further FDA involvement in the Laetrile controversy, it does not affect the validity of the various state legislative and judicial pronouncements on the legality of Laetrile. Despite the FDA's call for evidence of Laetrile's safety and effectiveness, seventeen states have legalized the drug. Pro-Laetrile campaigns were defeated, however, in fourteen states in 1978. [1978] FOOD DRUG COS. L. REP. (CCH) ¶ 42,292.

In other states, judicial decisions have paved the way for importation and distribution of the drug in specific instances. *See, e.g.*, People v. Privitera, 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (1977); Suenram v. Society of Valley Hosp., 155 N.J. Super. 593, 383 A.2d 143 (1977).

[3] 16 C.F.R. § 1207.7 (1977), *revoked*, 43 Fed. Reg. 58,813 (1978).

[4] Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831 (5th Cir. 1978).

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Department of Transportation's safety-belt/ignition interlock rule,[5] removed its authority to require helmets for motorcyclists,[6] and expressed distaste for its "air bag" regulation.[7] Congress has also rejected the proposed consumer-protection agency.[8] And the Federal Trade Commission's proposal to control television advertising of sugared cereals for children has prompted the *Washington Post* to accuse the agency of becoming the "national nanny." [9]

These events contrast sharply with those of just a few years ago, when Ralph Nader first argued that automobiles were "unsafe at any speed" [10] and the consumer movement demanded and received protection against business malfeasance and nonfeasance. Why the difference? What has changed?

Unfavorable economic conditions offer one explanation. Since 1973, oil embargoes, soaring prices, recessions, and high unemployment have plagued the country. Consumer protection was fine when the economy was buoyant, but in times of belt-tightening it is regarded as an unaffordable luxury, since its benefits are often less immediately apparent than its costs. When auto sales declined drastically during the 1974 recession, for example, Ford and Chrysler asked for a moratorium on federal safety and environmental standards. Chrysler threatened to close a Detroit auto plant employing 5,000 people in one of the city's poorer neighborhoods if the volume of auto sales did not increase. Eventually the industry got its way.[11]

Greater sophistication in the business community about lobbying and grass-roots politicking may also account in part for the decline in political support for consumer protection. Trade associations have flooded Washington in the past few years. Since 1969, four hundred corporations have opened Washington offices.[12] And it is estimated that corporations and trade associations account for eighty-five to ninety per cent of about $1 billion a year spent on grass-roots efforts.[13]

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[5] Motor Vehicle and Schoolbus Safety Amendments of 1974, Pub. L. 93-492, Title I, § 109, 88 Stat. 1482 (codified at 15 U.S.C. § 1410b (1976)).

[6] Highway Safety Act of 1976, Pub. L. 94-280, Title II, § 208(a), 90 Stat. 451 (codified at 23 U.S.C. § 402(c) (1976)).

[7] In 1977, the Senate sustained the Department of Transportation's decision to require air bags on 1984 models by a vote of 65 to 31. 123 CONG. REC. S17016 (daily ed. Oct. 12, 1977). The following year, however, Congress tacked on a rider to the Department's appropriations bill which provided that no funds could be used to enforce or implement the airbag requirement. Department of Transportation and Related Agencies Appropriation Act, 1979, Pub. L. 95-335, Title III, § 317, 92 Stat. 435. The House has added an identical amendment to the 1980 appropriations bill. 125 CONG. REC. H8066 (daily ed. Sept. 18, 1979).

[8] The bill to create the agency was defeated by a vote of 227 to 189. 124 CONG. REC. H828 (daily ed. Feb. 8, 1978).

[9] *The FTC as National Nanny*, Wash. Post, Mar. 1, 1978, § A, at 22, col. 1E.

[10] R. NADER, UNSAFE AT ANY SPEED (1965).

[11] *Business Lobbying: Threat to the Consumer Interest*, 1978 CONSUMER REP. 526.

There is, however, another critical factor. Underlying the economic and political shifts of recent years has been a growing public unease about the function of consumer protection. It is not so much that the goal worries people. Ask the average consumer whether he wants unsafe cars, carcinogenic drugs, adulterated foods, dangerous toys, or advertising intended to exploit the gullibility of his four-year-old and he will answer with a resounding "no." But ask him whether government regulators should intervene to remedy these problems and his response is likely to be ambivalent. Increasingly, the public debate about consumer protection has centered less upon the question of which marketplace evils should be cured than upon the propriety of having the government administer the remedy. In its crudest form the question has become: whom do you trust less—big business or big government?

To take sides in this debate would be foolish—recent history offers no particular reason for trusting in either big business or big government. Moreover, *some* government regulation will always be needed to make sure that consumers are getting what they pay for, even if it is limited to inspecting the scales at the checkout counter and testing for contaminates in beef.

Yet the current crisis in consumer protection points up the need for a reexamination of the fundamental questions. That some form of consumer protection is conceded to be necessary only begins the inquiry. *Why* do consumers need protection? *When* should the government intervene to protect them? *How* should it do so? The government's current answers to these questions have yielded a regulatory policy fraught with difficulties. The need for consumer-protection regulation is seen as arising from the sale of unsafe, unhealthy, or inefficient products. Relying on risk-benefit analyses, existing policy calls for government intervention whenever the cost of making a product better is less than the benefit to consumers of the extra margin of safety, health, or efficiency thereby achieved. Typically, government intervention takes the form of requiring manufacturers and sellers to bring their products in line with minimum official standards, or in some instances, of banning sales altogether.

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[12] *Id.* 527; *Washington Information Boom*, DUN'S REVIEW, March 1979, at 60.

[13] *Business Lobbying: Threat to the Consumer Interest*, 1978 CONSUMER REP. 526, 526. *See also* Epstein, *The Business PAC Phenomenon*, REGULATION, May-June 1979, at 35; *Washington Information Boom*, DUN'S REVIEW, March 1979, at 60.

The paternalism and potentially limitless opportunity for government intervention implicit in such an approach have, in turn, engendered a growing skepticism about the legitimacy of consumer protection, and thereby worked to the advantage of those organized interests hostile to the consumer movement.

This Article offers a way out of the current impasse by proposing a nonpaternalistic approach to consumer protection that takes account of the market's structure and its incentives.[14] The need for consumer protection lies not in the existence of "bad" products, but in market relationships which make it unlikely that sellers will take efficient steps to prevent consumer mistakes. This will occur in markets where sellers do not have a significant stake in maintaining goodwill. It follows that the current regulatory method of directly supervising the quality of the product misses the mark. The least costly and most effective strategy for consumer protection is to increase the stake which sellers have in building and maintaining goodwill.

No discussion of consumer-protection policy can afford to ignore antitrust considerations. Part I of this Article discerns the origins of consumer protection in regulatory efforts to restrain competition within temporarily unstable markets. Part II analyzes the contemporary "purchasing agent" model of consumer protection, whereby government directly assesses a product's costs and benefits and the costs and benefits of improving product quality. Because the "purchasing agent" model lacks any connection to the dynamics of the market, it is unable to provide a basis for integrating consumer-protection and antitrust policies, a problem explored in part II by examining four kinds of market restraints typically condemned by antitrust law without consideration of their potential for significant consumer benefits.

Part III sets forth a new, market-oriented analysis of *why* consumers need protection. Parts IV and V address the *when* and *how* of government intervention: Part IV identifies four market situations that reduce incentives to maintain goodwill; part V outlines a number of strategies for increasing the seller's stake in goodwill, a program consistent with the basic concerns of antitrust, as well as consumer-protection policy.

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[14] This Article does not consider the possible effects of consumer purchases on third parties. If one dwelled only on such effects, some justification for government paternalism might be discovered. After all, a child's dangerous toy can injure his friend as easily as himself, and not even the rational consumer is likely to weigh this possibility fully in his purchasing calculations.

I. CONSUMER PROTECTION AND MARKET INSTABILITY: GOVERNMENT AS FRANCHISOR

The American economy has paid lip service for two hundred years to the twin laissez-faire principles of vigorous competition and consumer self-reliance, the latter embodied in the maxim *caveat emptor*. But whenever major businesses faced unstable and uncertain markets, and consumers likewise confronted risky market decisions—when, in short, rapid social or technological change threatened long-standing and established business-consumer relationships—the government attempted to achieve stability by regulation. Government franchising in various guises served to promote consumer as well as private interests by restraining the operation of market forces. The murky origins of consumer protection are thus intimately bound up with protection of certain businesses from competition.

During the latter part of the eighteenth and the beginning of the nineteenth century, some of the nation's most rapidly changing and expanding businesses—banks, insurance companies, and steamboat, turnpike, and bridge operations—received exclusive franchises from state governments, assuring them both stable custom and freedom from local competition. In return, these businesses were vested with public responsibilities. In 1809, the Virginia Supreme Court of Appeals, upholding legislation amending the charter of an insurance company, made this quid pro quo explicit: "[acts of incorporation] ought never to be passed, but in consideration of services to be rendered to the public." [15] A few years later, New York's Chancellor Kent justified on a similar basis the finding of an implied monopoly in a corporate charter: "The consideration by which individuals are invited to expend money upon great, and expensive, and hazardous public works, as roads and bridges, and to become bound to keep them in constant and good repair, is the grant of a right to an exclusive toll." [16] The government thus agreed to restrict competition in these financial and transportation markets, so vital to a developing economy, in exchange for capital investment and a guarantee to the consuming public of safety and reliability.[17]

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[15] Currie's Adm'rs v. Mutual Assurance Soc'y, 14 Va. (4 Hen. & M.) 315, 347 (1809).

[16] President of the Newburgh and Cochecton Turnpike Road v. Miller, 5 Johns. Ch. 100, 111 (N.Y. Ch. 1821), *quoted in* M. HORWITZ, THE TRANSFORMATION OF AMERICAN LAW 1780-1860, at 126 (1977).

The period between 1870 and 1914 saw a great expansion of economic activity and the development of new markets in consumer goods and services; it also brought destabilization in the form of depressions and sharp upturns. A willingness to sacrifice competition in some industries in return for secure investment opportunities and consumer protection led to regulation. Principles of consumer and business protection, demanding government intervention and control over trade, coexisted peacefully with the principles of a free-market economy, which required unfettered contact among sellers and consumers. Tensions were avoided in large part because government intervention focused on particular markets where rapid growth, coupled with technological or social change, made participation risky for both business and consumers. Under those circumstances, unfettered competition rendered the outcomes of business-investment and consumer-purchasing decisions less predictable, and government regulation more palatable. Regulation thus served to fence in those providers who had been sufficiently bold or farsighted to make the initial investments, and to fence out the Johnny-come-latelies who otherwise would seek to exploit the new demand.

By the mid-1880s, for example, the established railroads faced new competition. They first reacted by attempting to create voluntary pools and agreements to prevent rate-cutting and raiding of established territories. These efforts failed, however, because of the legal unenforceability of such arrangements and the inability of the railroads to act in concert.[18] Finally, the established railroads advocated and helped to create the Interstate Commerce Commission.[19] In addition to promoting the railroads' private interests, federal regulation was intended also to end rate discrimination and to provide farmers, merchants, and consumers with consistent and high-quality rail service.[20] Similarly, from its inception the Civil Aeronautics Board served to protect the fledgling aviation industry against new entrants; but it served also to protect passengers from the potentially unsafe consequences of untrammeled competition.[21]

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[17] See M. Horwitz, The Transformation of American Law 1780-1860, at 109-39 (1977), for a discussion of the legislative and judicial roots of such agreements to restrict competition.

[18] G. Kolko, Railroads and Regulation 1877-1916, at 7-29 (1965); P. MacAvoy, The Economic Effects of Regulation: The Trunk-Line Railroad Cartels and the Interstate Commerce Commission Before 1900, at 25-109 (1965).

[19] G. Kolko, *supra* note 18, at 26-44.

A parallel development marked the growth of state occupational licensing statutes.[22] By 1900, Wisconsin had restricted entry into ninety trades, enacting occupational licensing requirements for attorneys, teachers, peddlers, public showmen, pharmacists, dentists, and doctors.[23] By 1915, druggists, osteopaths, midwives, embalmers, barbers, plumbers, accountants, real estate brokers, employment agents, and stockbrokers were added to the list.[24] By the 1950s, aircraft dealers, land surveyors, investment advisors, motor-vehicle salvagers and wreckers, cemetery salesmen, hunting and fishing guides, auto salesmen, auto auctioneers, and operators of commercial driving schools were among the occupations in Wisconsin governed by new or substantially revised legislation.[25] Typically, licensees were required to meet certain standards of safety and reliability; in return they received protection from potential competitors who did not meet these standards.[26] Such legislatively imposed occupational entry barriers usually were sustained by the courts as reasonable exercises of state police power.[27]

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[20] *See* J. Garraty, The New Commonwealth, 1877-1890 (1968):

> Although the commission [ICC] proceeded cautiously and some railroad executives failed to live up to the spirit of the new regulations, the commission's rulings had an immediate stabilizing impact on the transportation industry. By conducting investigations, collecting statistical data, and disseminating its findings widely, it made large strides toward forcing sounder financial practices on the railroads and encouraging them to rationalize their rate structures. Rate differentials between competitive and non-competitive points were reduced sharply. In some circumstances, the roads used the act as an excuse for resisting the demands of shippers for special favors. In countless subtle ways, it compelled railroad men to recognize some of their *public* responsibilities.

Id. 120 (emphasis in original). *See also* A. Kerr, Railroad Politics, 1914-1920 (1965); Carson, *Railroads and Regulation Revisited: A Note on Problems of Historiography and Ideology*, 34 Historian 437 (1972); T. Ulen, The ICC as Cartel Manager: Was It Necessary? (1977) (unpublished Ph.D. thesis, Stanford University).

[21] *See* W. Adams & H. Gray, Monopoly in America: The Government as Promoter 64-69 (1955); E. Smead, Governmental Promotion and Regulation of Business 280-81 (1969).

[22] See Council of State Governments, Occupational Licensing Legislation in the States 20-27 (1952), attributing the post-Civil War licensing legislation to the assumption by the states of "the responsibility of regulating the professions as a means toward greater protection of the public from incompetency, fraud, and quackery" and to the sponsorship of such legislation by occupational associations seeking to protect their levels of compensation and status. *Id.* 20-21. *See also* W. Horowitz, Occupational Licensing in Arizona (1966).

[23] L. Friedman, Contract Law in America 162 (1965).

[24] *Id.* 163-65. For surveys of similar movements in other geographic areas, see H. Alderfer, Professional Licensing in Pennsylvania (1962); M. Carrow, The Licensing Power in New York City (1968); W. Horowitz, Occupational Licensing in Arizona (1966).

[25] L. Friedman, Contract Law in America 170-71 (1965).

Although intended to protect from competition certain industries and occupations—interests which were able to mobilize political support for entry restrictions far more easily than consumers could have mobilized against them—the advantages that accrued to consumers from these measures support a theory of mutual benefit. Consumers in effect accepted higher prices in exchange for security against marginal operators, who might otherwise have taken advantage of rapid changes to defraud or endanger them.

These moratoria on competition often tended to last far longer than necessary to cope with any temporary market instability. Licensees and franchisees found the fruits of monopoly to be enjoyable; they relinquished them, if at all, only after a political struggle. Most "professions" today remain sheltered from competition, long after the need to attract and reward high quality work or to protect consumers from poor quality has abated.[28] Deregulation of interstate trucking has proved difficult, although little justification can be found for maintaining entry barriers in that industry.[29] Indeed, perhaps the realization of the political difficulty of removing an exemption from the competitive economy once granted, explains the shift in the focus of consumer protection in recent years from the performance of particular markets to the merits of particular products.

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[26] The relationship between consumer protection and restricted entry is well illustrated by the reaction of one Indiana barber to the licensing of his profession: "[I]t takes legislation to protect us from scab prices, pestilence and disease." *Id.* 163.

[27] *See, e.g.*, Baccus v. Louisiana, 232 U.S. 334 (1914) (ban on sale of drugs by itinerant vendors or peddlers); Crowley v. Christensen, 137 U.S. 86 (1890) (liquor licensing); Dent v. West Virginia, 129 U.S. 114 (1889) (physician licensing); Slaughter-House Cases, 83 U.S. (16 Wall.) 36 (1873) (exclusive slaughterhouse license). Notions of substantive due process surfaced occasionally to void various licensing statutes. Yet, even in these instances, the courts restricted their holdings to professions bearing little relationship to public health. *See, e.g.*, New State Ice Co. v. Liebmann, 285 U.S. 262, 277 (1932) (manufacture and sale of ice not sufficiently affected by public interest); State v. J. P. Harris, 216 N.C. 746, 6 S.E.2d 854 (1940) (licensing of dry-cleaning business unnecessary for public protection).

[28] *See* National Community Consumer Education Project, Occupational Licensing: A New Role for Consumers (1978).

[29] *See* A. Friedlander, The Dilemma of Freight Transport Regulation 133-55 (1969); Moore, *Deregulating Surface Freight Transportation*, in Promoting Competition in Regulated Markets 55-93 (A. Phillips ed. 1975).

II. CONSUMER PROTECTION AND PRODUCT INADEQUACY: GOVERNMENT AS PURCHASING AGENT

In the early days of consumer protection, the unstated principle guiding government interventions to protect consumers was to control the market instability which caused businessmen, investors, and consumers to feel particularly insecure in their relationships. The principle which has emerged during the last decade, however, has little to do with such instability. Instead, the government has increasingly assumed the role of purchasing agent, assessing the merits and demerits of particular products on behalf of consumers.[30] Meanwhile, competition policy, as shaped by the courts and antitrust enforcement agencies, has taken off on its own course, somewhat oblivious to consumer-protection interests.[31]

Corresponding to these developments, an analytic dichotomy has grown up between consumer-protection and competition policies. Law schools, for example, typically treat the two in separate courses; even when they are conjoined within the broad subject area of "trade regulation," they are treated as presenting quite separate issues. More serious for public policy, decisions to intervene in the economy on behalf of consumers have failed to take proper account of the market's structure and its incentives. As a result, the scope of government interference has acquired a limitless potential, and the government has sometimes intervened even though consumers themselves believe they need no protection. The following sections will serve to expand and clarify these points.

A. *Assessing the Costs and Benefits of Particular Products*

Within the last fifteen years Congress has enacted a startling amount of legislation governing the quality of particular products. Foremost has been product-safety legislation, including: The Poison

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[30] One commentator theorizes that modern consumer-protection regulation has created long-term, collective contracts between consumers and producers which are administered by regulatory agencies. These "administered contracts" entail rules which allow adjustments and compensation for unexpected costs. The rules also allocate anticipated risks and benefits and identify the circumstances in which the contract may be terminated. *See* Goldberg, *Regulation and Administered Contracts*, 7 BELL J. ECON. 426 (1976).

[31] For the view that competition policy in the Antitrust Division of the Department of Justice is indeed shaped by myriad factors unrelated to consumer-protection interests, see S. WEAVER, DECISION TO PROSECUTE: ORGANIZATION AND PUBLIC POLICY IN THE ANTITRUST DIVISION (1977). On the basis of extensive interviews with Division personnel, Weaver concludes, for instance, that Division attorneys adhere to a procompetitive stance, refusing to recognize that the value of competition may have to be balanced against other social or economic interests. *Id.* 169.

Prevention Packaging Act;[32] the Lead-Based Paint Poisoning Prevention Act;[33] the Consumer Product Safety Act;[34] the Highway Safety Acts;[35] and the National Traffic and Motor Vehicle Safety Act.[36] Other legislation has extended government involvement in product packaging, labeling, and disclosure,[37] and product warranties.[38] Entire agencies, such as the Consumer Product Safety Commission and the National Highway Traffic Safety Administration, have been established to assay products posing "unreasonable risk" of injury.[39] Older agencies, such as the Federal Trade Commission, have grown increasingly bold in regulating particular products deemed inadequate or unsafe.[40]

Mindful that consumers often bear the costs of consumer protection regulation, these agencies have applied increasingly elaborate risk- or cost-benefit analyses to products within their jurisdictions. In their role as "purchasing agents" they are assessing the health consequences of new drugs, foods, and cosmetics; the safety of toys, automobiles, and appliances; and the durability, efficiency, and reliability of a host of other consumer products. Regulatory tools are then fashioned for controlling the dissemination of products according to their relative risks and benefits.[41] In its recently unveiled

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[32] Pub. L. 91-601, 84 Stat. 1670 (1970) (codified at 15 U.S.C. §§ 1471-1476 (1976)).

[33] Pub. L. 91-695, 84 Stat. 2078 (1971) (codified at 42 U.S.C. §§ 4801-4846 (1976)).

[34] Pub. L. 92-573, 86 Stat. 1207 (1972) (codified at 15 U.S.C. §§ 2051-2081 (1976)).

[35] Pub. L. 89-564, 80 Stat. 731 (1966) (codified at 23 U.S.C. §§ 401-406 (1976)) (amended in 1970, 1973, 1976, and 1978).

[36] Pub. L. 89-563, 80 Stat. 718 (1966) (codified at 15 U.S.C. §§ 1381-1431 (1976)).

[37] *See, e.g.*, Federal Cigarette Labeling and Advertising Act, Pub. L. 89-72, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331-1340 (1976)); Fair Packaging and Labeling Act, Pub. L. 89-755, 80 Stat. 1296 (1966) (codified at 15 U.S.C. §§ 1451-1461 (1976)); Motor Vehicle Information and Cost Savings Act, Pub. L. 92-513, 86 Stat. 947 (1972) (codified at 15 U.S.C. §§ 1901-2012 (1976)).

[38] *See* Magnuson-Moss Warranty—Federal Trade Commission Improvement Act, Pub. L. 93-637, 88 Stat. 2183 (1975) (codified at 15 U.S.C. §§ 2301-2312 (1976)).

[39] *See* 15 U.S.C. § 2057 (1976) (applying "unreasonable risk" standard to Consumer Product Safety Commission); 23 U.S.C. §§ 401-406 (1976) (applying "unreasonable risk" of accident standard contained in National Traffic and Motor Vehicle Safety Act, 15 U.S.C. §§ 1381, 1391 (1976), to National Highway Traffic Safety Administration).

[40] *See* SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94TH CONG., 2d SESS., REPORT ON FEDERAL REGULATION AND REGULATORY REFORM 57-110 (Subcomm. Print 1976).

[41] See REGULATING THE PRODUCT (R. Caves & M. Roberts eds. 1975) for a collection of papers addressing the effect of various control mechanisms on product quality.

Long-Range Planning Options report, the Consumer Product Safety Commission's Office of Strategic Planning recommends, for example, that the agency adopt as its highest priority the reduction of "the unreasonable risk of injury from product hazards, with due regard to the social and economic impacts of government action."[42] Similarly, the National Highway Traffic Safety Administration's newly announced Five-Year Plan bases its regulatory priorities on an assessment of the "lifesaving potential of a safety standard" and the "anticipated costs to consumers and industry."[43] The Commissioner of the Food and Drug Administration recently stated, meanwhile, that "risk-benefit balancing must be done for drugs because there is no such thing as a 'safe' drug."[44] Congress soon will begin a major review of the Delaney amendment, which flatly prohibits any food additive that "induces" cancer in man or animals, with a view toward authorizing the FDA to regulate additives according to benefits and risks.[45] And the Federal Trade Commission has been attempting to ensure that the benefits of its interventions substantially outweigh whatever increased product costs are thereby passed on to consumers.[46]

In general, government intervention under this "purchasing agent" model is presumed to be desirable whenever product risks are reduced by the proposed regulation to a greater extent than costs are added.[47] The greater the disparity between these two measures, the more extreme the regulatory response. Outright bans of products are thought to be necessary whenever the risk and magnitude of physical or economic harm thereby avoided is deemed substantially greater than product benefits foregone. Regulators have placed within this category unvented gas space-heaters, lead-based paint, saccharin, and certain drugs. Design specifications or performance standards are thought to be appropriate when the disparity between product risks and benefits is less, but nevertheless significant, as with "childproof" aspirin bottles, flame-resistant sleepwear, nitrites in bacon, rotary lawnmowers, and auto seat belts and airbags. Bans on advertising may be justified in cases where the risk-benefit difference is still less determinative, but the risks remain of major concern, such as television advertising of cigarettes, children's cereals and candy, or alcohol. Mandatory disclosures in advertising or on labels are thought appropriate when risks and benefits, although substantial, are closely balanced, as, for example, with food ingredients, blood from paid or volunteer donors, and energy efficiency of home appliances.[48]

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[42] Office of Strategic Planning, Consumer Prod. Safety Comm'n, Long-Range Planning Options (1978). At the CPSC, application of a risk-benefit approach has been facilitated by the courts. In Forester v. Consumer Prod. Safety Comm'n, 559 F.2d 774 (D.C. Cir. 1977), the court defined "unreasonable risk" in the Federal Hazardous Substances Act, 15 U.S.C. § 1261(s) (1976), as involving "a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Id.* 789 (footnote omitted). *Cf.* Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831 (5th Cir. 1978) (Commission's finding that safety standard was reasonably necessary to eliminate or reduce unreasonable risk of injury not supported by substantial evidence).

[43] National Highway Traffic Safety Ad., Dep't of Transp., Five-Year Plan (1978).

[44] Food Chemical News, Feb. 27, 1978, at 32. *See also* Hutt, *Unresolved Issues in the Conflict Between Individual Freedom and Government Control of Food Safety*, 33 Food Drug Cosm. L.J. 558 (1978).

[45] *Congress Plans Major Review of Food Laws*, 1979 Cong. Q. 230.

[46] *See, e.g.*, Advertising of Ophthalmic Goods and Services, Notice of Proceeding and Proposed Trade Regulation Rule, 41 Fed. Reg. 2399, 2400-01 (1976).

[47] The cost of regulation should include, of course, any foregone product benefits. For an early statement of this formulation, see United States v. Carroll Towing Co., 159 F.2d 169 (2d Cir. 1947).

This "purchasing agent" model of government intervention is, of course, open to the charge that it imposes additional costs upon members of the consuming public who, because they can use dangerous products more carefully or skillfully than others, or can make repairs more cheaply, or because they care less about physical and economic harms than other people do, would prefer not to pay more for the safer, healthier, more reliable, or more fully labeled product. Moreover, according to this argument, it is unnecessary to impose the costs of consumer protection on these voluntary risk-takers for the sake of protecting those risk-avoiders whose preferences more closely resemble the government's; presumably those risk-avoiding consumers would have opted for the safer, healthier, more reliable, or more fully labeled product on their own.

But this view ignores the fact that the market for consumer goods is less than perfect, and often cannot be relied upon to generate the degree or quality of information consumers need in order to make rational purchasing decisions. Product choice in some markets remains limited: risk-avoiding consumers seeking a safe automobile have no opportunity to choose a safer, more costly bumper from the restricted range of offerings produced by an oligopolistic industry.[49] Moreover, even under competitive conditions, sophisticated advertising and promotional techniques may well manipulate and ultimately distort consumer demand.[50]

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[48] Professor Richard Wilson has urged that, based upon linear extrapolation from animal testing, activities or products which create a 1-in-100 chance of death or serious injury with each discrete usage should be banned, while those which create a risk of less than 1 in 100,000 should be regarded as acceptable. For activities or products between those two levels, public education and warnings are appropriate. Testimony of Richard Wilson Before the Occupational Safety and Health Administration (Feb. 10, 1978) (OSHA Docket No. H-090) *cited in* Hutt, *supra* note 44, at 582-83.

A more sophisticated analysis, however, reveals flaws in the "purchasing agent" model which stem from its antagonism to certain fundamental principles of American political economy. First, even if the government's calculations could exactly predict the quality of products and information that rational consumers would choose in a perfect market, the very insistence that government planners and policymakers intervene on behalf of consumers implies that consumers are unable to take care of themselves. Substitution of the choices of bureaucrats for those of consumers carries with it a not so subtle implication that consumers are relatively powerless, if not incompetent, when faced by the combined force of corporate greed and Madison Avenue hype. That message is apt, at the very least, to offend consumers' self-esteem. A saccharin ban implies that consumers cannot be trusted properly to weigh the risks of saccharin, just as a ban on television advertising to children implies that parents cannot be trusted to control their children's viewing. The charge of "big brotherism" in this context may come less as a total rejection of consumer protection than as an affirmation of a preferred self-image of competence. Consumers are not dumb; they recognize that bureaucrats, too, are fallible people, not necessarily more competent than the consumers they purport to protect.

Second, a consumer-protection policy based on a bureaucratic calculus of risks and benefits has no principled limits. Once it is accepted that the government can intercede between consumers and sellers whenever intervention can produce "better" purchasing decisions, no obvious stopping-place can be found. Such a rationale opens the entire economy to scrutiny. It suggests that products are "unsafe" or "defective" whenever the cost of making them safer or more durable is less than the value, as measured by regulators and policymakers, of the extra safety or durability thereby achieved. Similarly, it suggests that sellers should be required to provide more or higher quality product information whenever the cost of generating and communicating it is less than the value to the consumer, again as measured by regulators and policymakers, of acquiring it. At bottom, the risk-benefit rationale for intervention approximates the kind of calculation that consumers traditionally make when they choose a product, choose to do without it, or decide to consult first with friends or *Consumer Reports* before purchasing. But, because bureaucrats rather than consumers undertake the calculation, the risk-benefit rationale becomes a veritable slippery slope.

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[49] Albert Hirschman's juxtaposition of two consumer complaints to Ford and General Motors, with each consumer threatening to purchase from the other manufacturer in the future, is a telling illustration of the consumer's bind. Without regulation, an oligopolistic market cannot be relied upon to satisfy both the risk-avoider and risk-taker. *See* A. HIRSCHMAN, EXIT, VOICE, AND LOYALTY 27 n.7 (1970).

[50] *See, e.g.,* S. EWEN, CAPTAINS OF CONSCIOUSNESS: ADVERTISING AND THE SOCIAL ROOTS OF THE CONSUMER CULTURE (1976); J. GALBRAITH, THE AFFLUENT SOCIETY 149-54 (2d rev. ed. 1969); J. GALBRAITH, THE INDUSTRIAL STATE 272-73 (1967).

Instead of merely correcting those market imperfections which prevent consumers from making rational purchasing decisions, the "purchasing agent" approach to consumer protection goes much further; it replaces the decisions of consumers in the marketplace with government edicts, a method whose premise is fundamentally incompatible with the liberal assumption that each person is the best judge of his or her own needs.

If this underlying contradiction escaped attention fifteen years ago when consumer protection began focusing upon the merits of particular products rather than the stability of particular markets, perhaps it was because there were enough egregious abuses to justify ad hoc government interventions without appeal to any overreaching principle. The list of horribles included unsafe automobiles, teratogenic (fetus-deforming) drugs, deceptive advertisements, injurious rotary mowers, and schemes to sell worthless real estate. But the bureaucracy of consumer protection has grown in the past few years. The occasions for intervention have now extended beyond those most serious cases to instances which may be less compelling on their facts and more in need of a new and principled rationale. The current rationale is simply too grandiose and overreaching to coexist peacefully with principles of a free-market economy.

B. *Accounting for the Consumer-Protection Potential of Various Market Restraints—An Unfulfilled Need*

As the focus of consumer protection has shifted from markets to products, its rationale has lost any logical connection with the existence or nonexistence of competition. Accordingly, no coherent theory has emerged to explain how, and under what circumstances, various restrictions on competition might help ensure or inhibit the fulfillment of consumer expectations. Competition policy, aimed relentlessly at market power in any guise, has not had to compete with, or comprehend, a market-based rationale for consumer protection because none has been articulated. This has unfortunately left courts and policymakers free to ignore situations in which certain restrictions on competition can work to the benefit of consumers. A brief survey of the current status of four potentially pro-consumer market restrictions—market division agreements, tying arrangements, occupational licensing, and trademark protection—shows that existing law and policy lack the basic analytical tools needed to understand the interplay between competition and consumer protection.

1. Market Division Agreements

Market-division agreements can make it profitable for an outlet within one vicinity to cooperate with outlets in others. Because such agreements ensure that each outlet's investment redounds to its own benefit rather than to the benefit of "free riders" selling the same product nearby, each has an incentive to promote the product and maintain uniform quality.[51] Notwithstanding this potential consumer benefit, market-division agreements have been deemed illegal. In *United States v. Sealy, Inc.*,[52] for example, the Supreme Court determined that the territorial agreements by which Sealy limited its manufacturer-licensees to sales in designated territories "gave to each licensee an enclave in which it could and did zealously and effectively maintain resale prices, free from the danger of outside incursions."[53] Finding this a sufficient connection with price fixing, the Court applied the rule of per se illegality to hold the agreements "unlawful under § 1 of the Sherman Act without the necessity for an inquiry in each particular case as to their business or economic justification, their impact in the marketplace or their reasonableness."[54] Application of the per se illegality test thus caused the Court to ignore the potential benefits from the market-division agreements, including the possibility that they would help to ensure the uniformity of products appearing under the licensed name and trademark. This test ignored also the district court's findings, never disputed by the government, that the agreements permitted national distribution of the uniform product and made it profitable for each licensee to contribute to national advertising, research, and promotion.[55]

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[51] The Supreme Court discussed this "free rider" effect in its recent opinion in Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 55 (1977).

[52] 388 U.S. 350 (1967).

[53] *Id.* 356.

[54] *Id.* 357-58. The *Sealy* majority found the challenged arrangement a thinly disguised horizontal agreement among Sealy's manufacturer-licensees. Sealy was owned and directed almost entirely by the owners and operators of its licensees. Consequently, according to the majority, the agreements were in substance, if not in form, agreements among the manufacturers operating as equals in a competitive market. As horizontal restraints, the licensing agreements were subject to a more stringent standard—traditionally, a per se standard—than applied to vertical restraints.

In a lone dissent, Mr. Justice Harlan argued that Sealy's territorial divisions were *vertical* restraints and not, therefore, illegal per se. He noted also that such agreements tended to increase general market competition by sharpening Sealy's competitive edge, especially since Sealy did not dominate the relevant market. *Id.* 361 n.2. See Pitofsky, *The* Sylvania *Case: Antitrust Analysis of Non-price Vertical Restrictions*, 78 COLUM. L. REV. 1 (1978), for a discussion of the distinction between vertical and horizontal restrictions, as well as mention of the consumer benefits from certain types of market restraints.

The Supreme Court recently determined, in *Continental T.V., Inc. v. GTE Sylvania, Inc.*,[56] that some vertical market divisions are legal, in part, because they serve to "promote interbrand competition by allowing the manufacturer to achieve certain efficiencies in the distribution of his products."[57] Although it remains to be seen what sorts of market-division agreements or other vertical restraints will pass muster, presumably those which create efficiencies in maintaining product quality within the distribution process should no longer be deemed illegal per se—particularly if the manufacturer has no reasonable alternative means of ensuring quality.[58]

2. Tying Arrangements

Tying arrangements, like agreements to divide markets, also may protect consumers from poor maintenance or servicing of products. But the courts have tended to strike down these arrangements without regard to potential consumer-protection benefit. In *United States v. Jerrold Electronics Corp.*,[59] for example, the court found illegal a tying arrangement through which Jerrold sold whole antenna systems only on condition that it install and service them itself and replace any parts with Jerrold equipment. Although the court did recognize that the arrangement guarded against unsatisfactory performance resulting from system installation and servicing by companies lacking the requisite knowledge and skill, the court perfunctorily determined that this did not justify the tying arrangement in the already mature community-antenna industry.[60] In drawing its conclusion, the *Jerrold* court assumed, but certainly did not prove, that consumer-protection interests would be served adequately by independent servicing. It ignored the considerable goodwill interest that any manufacturer, whether in a young or mature industry, has in maintaining its own product: the independent serviceman can always blame his failures on product quality, a luxury the manufacturer does not enjoy.

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[55] *Id.* 358-62.

[56] 433 U.S. 36 (1977).

[57] *Id.* 54.

[58] Vertical restraints have been upheld where they are related to product safety, have no anticompetitive effect, and are ancillary to the seller's main purpose of protecting the public from harm or itself from product liability. *Id.* 55 n.23. *See* Tripoli Co. v. Wella Corp., 425 F.2d 932 (3rd Cir.) (en banc) *cert. denied*, 400 U.S. 831 (1970). *See also* Pitofsky, *supra* note 54.

[59] 187 F. Supp. 545 (E.D. Pa. 1960), *aff'd per curiam*, 365 U.S. 567 (1961).

[60] *Id.* 557, 558.

3. Occupational Restrictions

Occupational restrictions, in the form of state licensing laws and so-called "ethical" restraints imposed by professional associations, have traditionally been justified on the assumption that they protect consumers. But such restrictions have increasingly come under antitrust fire. The Federal Trade Commission has challenged certain state occupational licensing laws as unfair trade practices.[61] Both the Commission and the Antitrust Division of the Department of Justice have challenged "ethical" restrictions on the delivery of professional services.[62] Although these challenges have attempted to compare the benefits of competition with the costs to consumers of inadequate service which might follow the lifting of restraints, there has been no method for deciding which licensing statutes should be challenged in the first place. Because consumer-protection policies have lacked any dynamic market theory, it remains unclear when natural market incentives alone can be relied on to protect consumers without licensing, or when licensing may be the most efficient means of doing so.

Indeed, the Supreme Court has rejected any balancing of the benefits to consumer .protection when "ethical" restrictions are challenged under section 1 of the Sherman Act.[63] In *National Society of Professional Engineers v. United States,*[64] the government brought a civil antitrust action against the professional association; the association's canon of ethics prohibited competitive bidding by its members, and the government alleged that this restriction violated the Sherman Act. As an affirmative defense, the association contended that the canon was a reasonable restraint of trade because it minimized the risk to public safety that competitive bidding would induce engineers to cut prices and provide dangerously low-quality services. The district court granted an injunction against enforcement of the canon, and the court of appeals affirmed.[65] Acknowledging that there was a risk that competition would cause some suppliers to market a defective product and that the association had provided ample documentation to support its position,[66] the Supreme Court nevertheless unanimously affirmed. The Court reasoned that restraints of trade under the Sherman Act may be deemed reasonable only insofar as they promote competition, not because they protect consumers from dangerous products. "The judiciary cannot indirectly protect the public against [potentially defective products] by conferring monopoly privileges on the manufacturers." [67]

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[61] *See, e.g.,* Disclosure Regulations Concerning Retail Prices for Prescription Drugs, Proposed Trade Regulation Rules, 40 Fed. Reg. 24,031 (1975), *withdrawn,* 43 Fed. Reg. 54,951 (1978); Advertising of Ophthalmic Goods and Services, 16 C.F.R. § 456 (1979); Funeral Industry Practices, Trade Regulation Proceeding, 40 Fed. Reg. 39,901 (1975) (to be codified in 16 C.F.R. § 453).

[62] *E.g.,* National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679 (1978); American Medical Ass'n, No. 9064 (F.T.C., complaint issued Dec. 19, 1975), [1973-1976 Transfer Binder] TRADE REG. REP. (CCH) ¶ 21,068.

[63] 15 U.S.C. § 1 (1976).

[64] 435 U.S. 679 (1978).

4. Trademark Protection

Notwithstanding their potential importance to consumers in ensuring consistent quality and reliability,[68] trademarks also have been the object of antitrust attacks. In one recent FTC order, an administrative law judge found that Borden, Inc. had unlawfully maintained a monopoly position in the processed lemon industry.[69] In addition to a preponderant market share, the judge found to be "strongly demonstrative of monopoly power" the "overwhelming dominance of the ReaLemon brand, . . . its acceptance over the years by the trade and the public as the premium brand" and the premium price it commanded.[70] Ignoring the fact that this premium price may well have represented what consumers were willing to pay for consistent quality, the judge's reasoning proceeded strictly according to competition theory: "the heart of the monopoly power preserved and maintained by respondent Borden lies in the ReaLemon trademark and its dominant market position. For competition to enter the processed lemon juice industry, the barrier to entry which inheres in the ReaLemon trademark must be eliminated."[71] Accordingly, the judge required Borden to license use of its ReaLemon trade name.

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[65] The district court made no finding as to the risk that competitive pressures would result in the design of inefficient and unduly expensive structures, finding instead that the canon was illegal on its face. *Id.* 684-86.

[66] *Id.* 694.

[67] *Id.* 695-96.

[68] *See* Schmalensee, *On the Use of Economic Models in Antitrust: The ReaLemon Case*, 127 U. PA. L. REV. 994, 1036 (1979).

[69] Borden, Inc., No. 8978, slip op. at 167 (F.T.C., Aug. 19, 1976) (ALJ decision), [1976-1979] 3 TRADE REG. REP. (CCH) ¶ 21,194, *modified*, (F.T.C., Nov. 7, 1978) (opinion of the Comm'n), [1976-1979] 3 TRADE REG. REP. (CCH) ¶ 21,490.

[70] *Id.*

Although the remedy of compulsory licensing was rejected by the full Commission on appeal,[72] that action merely reflected the Commission's view that licensing was unnecessary to curb Borden's monopoly. Like the administrative law judge, the Commission made no attempt to evaluate the possible value of trademark protection to consumers.[73]

This, then, is a brief survey of the present state of consumer-protection competition policy. Under a "purchasing agent" model, government has increasingly intervened to regulate distribution of particular products or services, restrained only by a balancing of the costs and benefits of intervention. Objections to the paternalism inherent in this approach are compounded by its illimitable sweep. Antitrust policy, on the other hand, has ignored the goal of protecting consumers against such "bad" purchases, possibly because no criteria have been proposed for deciding under what circumstances undercompetitive markets protect consumers more or less efficiently than fully competitive ones.

Having now considered the evolution of consumer protection, a rethinking of its fundamentals is in order. What criteria should guide government decisions to intervene on behalf of consumers? Once a decision to intervene is made, what form should the intervention take? Before these questions can be answered, however, it is necessary to arrive at an understanding of why consumers need protection, and what the goal of government intervention ought to be.

III. The Goal of Consumer Protection

Consumer-protection policy has suffered at bottom from a confusion about goals. An implicit assumption of the "purchasing agent" approach is that consumers cannot be trusted to make rational purchases.[74] Therefore, to protect consumers, government must intervene to monitor the quality of products and services sold in the market. In essence, the "purchasing agent" rationale is an extension of paternalistic government efforts to protect consumers from the consequences of their own appetites—such as preventing consumers from buying sex, marijuana, pornography, or liquor.

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[71] *Id.*

[72] Borden, Inc., No. 8978 (F.T.C., Nov. 7, 1978) (opinion of the Comm'n), [1976-1979] 3 Trade Reg. Rep. (CCH) ¶ 21,490.

[73] The economic implications of heavily advertised brand names and trademarks are the subject of heated debate among economists. *See* W. Comanor, & T. Wilson, Advertising and Market Power 8-63 (1974); J. Ferguson, Advertising and Competition: Theory, Measurement, Fact 15-53 (1974); Brozen, *Entry Barriers: Advertising and Product Differentiation*, in Industrial Concentration: The New Learning 115 (H. Goldschmid, H. Mann & J. Weston eds. 1974).

[74] *See* text following note 50 *supra*.

An approach to consumer protection more sympathetic to liberal free-market principles that govern the American economy is possible. The problem lies not with "bad" products or irrational consumers, but in certain market conditions which do not provide sellers with sufficient incentive to prevent rational consumers from making costly mistakes. A consumer-protection rationale focusing on the likelihood that consumers within particular markets will misestimate physical or economic risks attendant upon their purchases can provide a strong basis for government intervention, untainted by paternalism.

A. *Hidden Costs and the Costs of Information*

Consumers bear several related costs when they purchase goods or services, only the most visible of which is the purchase price. Other costs are often hidden: the product may cause bodily injury, impair health, or damage property; it may require expensive or time-consuming maintenance or have to be totally replaced in a relatively short time; it may require enormous amounts of fuel; or it may be inadequate to perform the tasks that the consumer has in mind, requiring the consumer to forego those tasks or spend more to perform them.

The rational consumer [75] will wish to minimize the product's total cost (its purchase price plus these hidden costs), while at the same time receiving a product that fulfills his needs. But to accomplish this goal, he must bear still other costs. First, he must define his needs. Diagnostic information, which identifies and measures such particular requirements, can be expensive. To avoid gastric upset, the consumer may, for example, have to undergo a battery of tests to determine what foods his stomach cannot abide; similarly, to avoid the possibility that a newly purchased waterbed will crash through the ceiling, the consumer may have to employ a structural engineer to measure the tolerance of his upstairs floor. Second, after discovering his particular needs, the consumer must learn the capabilities of different products to fulfill those needs.

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[75] The "rational consumer" is of course a fiction; no one contends that consumers are actually as rational as this hypothetical person. Nonetheless, the concept can be useful in predicting general patterns of behavior.

Product-testing information, revealing, for example, the contents of a particular can of food or the fully inflated weight of a particular waterbed, also can be costly. Third, for the diagnostic and product-testing information to be useful, the consumer must have meaningful access to it in a timely manner. Communication, in the form of product advertising and consumer searching, is then a third related cost.[76]

For some purchases, the combined costs of diagnosis, product testing, and communication may exceed any savings in the total cost of the product sought. But it would be nonsensical for a consumer to expend more resources trying to locate a product than the potential savings available from its use. If, for example, a consumer has discovered three adequate lawnmowers of equal price, the best of which would save him one dollar in convenience and quality, there is no reason to spend more than one dollar to discover which of the three is truly best. Accordingly, a rational consumer will purchase product information only to the point at which the marginal cost of obtaining that information is likely to exceed any marginal gain in the total value of the product.[77] Thus, the "best" purchasing decision is not best in absolute terms, but only relative to the cost of the diagnosis, product testing, and communication necessary to make it. That some consumers may accept high total costs, in the form of dangerous, inadequate, or high energy-consuming products, does not necessarily indicate that the market is functioning inefficiently, for such a choice may reflect a rational trade-off against even higher information costs.

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[76] A slightly different typology has been used by Nelson, who distinguishes between "search qualities"—qualities of a product that the consumer can determine prior to purchase—and "experience qualities"—qualities that the consumer cannot determine prior to purchase. Nelson, *Advertising as Information*, 82 J. POL. ECON. 729, 730 (1974); Nelson, *Information and Consumer Behavior*, 78 J. POL. ECON. 311, 312 (1970). Darby and Karni use the term "credence qualities" to describe qualities that cannot be evaluated through normal use of a product, but can be assessed only by gaining additional costly information. Darby & Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J.L. & ECON. 67, 68-69 (1973).

[77] This model of course simplifies both the economics and the psychology of consumer search. The marginal-value/marginal-cost calculation is not strictly applicable to non-searchers. Given the presence of at least some consumer searchers, non-searchers can secure the benefits of product information without sustaining any costs, as producers are likely to compete for the searchers' business while offering the same terms to non-searchers. *See* Salop & Stiglitz, *Bargains and Ripoffs: A Model of Monopolistically Competitive Price Dispersion*, 44 REV. ECON. STUD. 493, 493-95, 501 (1977); *see also* Rothschild, *Models of Market Organization With Imperfect Information: A Survey*, 81 J. POL. ECON. 1283 (1973). But the notion that producers will compete for searchers' business may not extend fully to those markets in which hidden costs are excluded from the purchase decisions of all but the most scrupulous searchers. In these instances, producers may compete only as to price, with poor quality or substandard performance prevalent throughout the market. *See* text accompanying notes 81-86 *infra*.

For a recent study of the economics of information, see Schwartz & Wilde, *Intervening in Markets on the Basis of Imperfect Information: A Legal and Economic Analysis*, 127 U. PA. L. REV. 630 (1979). *See also* Katona & Mueller, *A Study of Purchase Decisions* in CONSUMER BEHAVIOR: THE DYNAMICS OF CONSUMER REACTION 30, 49, 52, 79-80 (L. Clark ed. 1954); Stigler, *The Economics of Information*, 69 J. POL. ECON. 213 (1961).

It follows that a range of less costly products, with "cost" again including potential hidden costs, will require less costly attempts to ensure that the purchasing decision is a proper one. If the price of the product is low, and the possible adverse consequences of a bad choice are minimal, the consumer's own diagnosis may be completely adequate ("I know what kind of food agrees with me"); as well as his own search ("Let's see if there's a restaurant in the neighborhood"); and his own testing ("It looks like a dive, but I'll try it once"). Alternatively, consumers might rely on the judgment of trusted friends, who are aware of their particular needs ("You'll love the ambiance, but don't eat the goulash"). If the product proves worthy, then the cost of diagnosing, testing, and locating it in the future can be greatly reduced by merely repurchasing it. Indeed, the business value of the "goodwill" derived from an established trade name or marketing technique is that consumers are willing to pay a premium for what they save by avoiding costly diagnosing, product testing, and searching.[78]

Occasionally, of course, it is more reasonable to look elsewhere for reliable information. When an incorrect purchasing decision could pose high risks to health or property, or could result in substantial economic loss, self-diagnosis or self-testing is unwise. Prudence would dictate, for example, that one seek expert advice about the need for maintenance or repair of complex machinery such as an automobile, home plumbing, or one's own body. Similarly, it is advisable to refrain from ingesting unidentified pills or investing a small fortune in an untested machine "just to see if it works," and to rely instead on tests performed by others. Indeed, it is often necessary for sellers to offer new products at a discount or to guarantee "complete satisfaction or your money back" in order to offset consumers' understandable reluctance to sail such uncharted seas. By the same token, if the sources of diagnostic or product-testing information are scattered, but the group of consumers who want the information are identifiable and can be reached through some common medium, it may be more efficient for the sources to communicate their information than for the consumers to spend their own time and resources trying to locate the sources. For example, a shipper specializing in Caribbean cruises could locate prospective purchasers by advertising in the *New Yorker* far more efficiently than prospective purchasers could locate him by writing to shipping companies.

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[78] To be sure, advertising may be used to establish goodwill. Although the product image created by advertising may substitute for product quality, "informative advertising" may serve a useful purpose when employed by new entrants to identify an established producer who has chosen to "rest on his laurels" rather than maintain consistent quality. Boyer, *Informative and Goodwill Advertising*, 56 REV. ECON. & STAT. 541 (1974).

Some sources of diagnostic and testing information sell nothing but such information, with the consumer paying primarily for reliability and good judgment. Consumer guides, independent testing laboratories, newspaper reviewers, and various types of appraisers fit within this category, as do, on a slightly more general level, training manuals, adult-education courses, and how-to-do-it books. Because property rights in such information are limited, however, and difficult to enforce against a recipient who is apt to share the information freely with others,[79] often only those sources who also have a pecuniary interest in the products under scrutiny can bear the direct cost of developing and communicating diagnostic and testing information. Some of these information sources function in effect as agents, and select products on behalf of consumers. In exchange, they charge consumers a premium for the quality of their selection. Travel agents, stock brokers, realtors, and department stores all bear most of the direct costs of developing product information and then pass these costs on to the consumers who find it more efficient to rely upon such intermediaries than to carry on their own diagnoses, tests, and searches. Alternatively, reliable information about product risks or inadequacies can sometimes be derived from competitors, for whom the cost of developing such information may be less than the expected revenues generated from sales of their own product.

Because they have direct access and control, sellers often can generate test information about their products more efficiently than any other source. They can run tests as a routine step in the production or marketing process, and they are aware of the particular product characteristics that require most careful attention. Similarly, sellers of maintenance or repair services often can generate diagnostic information more efficiently than other sources because they can both diagnose and respond to a particular need in a single transaction.

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[79] *See generally*, THE ECONOMICS OF PROPERTY RIGHTS (E. Furubotn and S. Pejovich eds. 1974).

B. *Minimizing Consumer Misestimation of Hidden Costs*

With this understanding of the role of product information in purchasing decisions, it becomes apparent that rational consumers will select the source of information that is both least expensive and most reliable, relative to the total product cost at stake. The sources of such information likewise can be expected to bear the direct cost of producing it only insofar as consumer demand yields adequate revenues. In this way, the information market should generate approximately the "right" amount of reliable information to enable consumers to make adequately informed purchasing decisions.

Under perfect marketing conditions, then, government intervention to protect consumers would be unnecessary. One could assume that consumers get just the amount of product information they need, and that they make rational trade-offs between product information, product quality, and purchase price. But consumers may, for a variety of reasons, underestimate the risk of economic loss or personal injury attendant upon their purchasing decisions. Sufficient product information may be unavailable or, if available, may be misconstrued. Or consumers may overestimate the reliability of the diagnosis or product-testing information received. Either way, they will miscalculate how much additional information they need—how much care they should exercise—before purchasing.

The problem then lies not in a particular product or service which appears to be inadequate, defective, unhealthy, inefficient, or unsafe. All these adjectives convey relative concepts which lack meaning outside the particular set of expectations which frames the transactions. Manufacturers and sellers make countless decisions to substitute lower cost for a higher-quality product or product information, and there is nothing inherently wrong about these decisions. Rather, problems arise when consumers, unaware of such substitutions, are unpleasantly surprised by poorer quality (higher hidden costs) than they bargained for. Skateboards, kitchen knives, waterbeds, "gas-guzzlers," and hang-gliders all can have disastrous consequences, but they present little justification for government intervention because consumers are apt to know of their risks and costs at the time of purchase.[80] On the other hand, life-insurance policies, home insulation, drugs and food additives are more obvious targets for government intervention because consumers are likely to underestimate the riskiness and costliness of these products.

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[80] With regard to some products, consumers know only of the existence of risks. They remain uncertain as to their distribution and unable to assess these risks accurately because all relevant information is possessed by the seller. The ways in which "imperfect information" may lead to market failures are discussed in Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970).

To be sure, the magnitude of the potential risk and the gravity of the harm are important considerations in deciding the appropriateness of intervention. A relatively small chance that consumers will underestimate these measures may nevertheless require intervention if risk and harm are substantial. The point is that it is the ignorance of consumers, rather than the product's intrinsic risk, which triggers the inquiry into the need for government action.

Misestimations of reliability of information or risk of loss could be reduced, if consumers or sellers, or both, were required to exercise more care in their transactions; but how much care, and who should exercise it, are complex issues. The ultimate question is not whether *caveat emptor* or *caveat venditor* is the correct principle, but under what circumstances and to what extent one principle is to be preferred to the other. If consumers and sellers could bargain with each other over the allocation of this responsibility, free from the costs of transacting those bargains, presumably they would allocate the responsibility to the party in the best position to minimize the likelihood of misestimations. In fact, buyers and sellers in large-scale commercial transactions do bargain over such responsibilities and risks. In the real world of unequal bargaining power and lack of coordination among consumers, however, liability rules may be necessary to allocate responsibility between the parties. Common law causes of action sounding in contract or tort in effect require the seller to bear the cost of fulfilling consumer expectations that his product is fit for ordinary use and not unreasonably dangerous, unless the seller gives warning that the product is being sold "as is" or presents unusual risks. But in other circumstances, the costs of private litigation are likely to be prohibitive, and more direct forms of government regulation may be desirable.

Viewed in this light, the purpose of government intervention should not be to protect consumers from purchasing "bad" products. Rather, the goal of consumer protection should be to minimize the likelihood that consumers will misestimate product risks and hidden costs, by placing the responsibility for avoiding such misestimations on sellers and manufacturers when they are better able to do so than consumers. This principle stands in sharp contrast to the "purchasing agent" model, which allows the government to intervene whenever it decides that the costs of a given product, including hidden costs, outweigh its benefits. Here, intervention is appropriate only when it cannot be presumed that sellers will voluntarily seek to prevent consumer misestimations.

IV. WHEN IS INTERVENTION APPROPRIATE?

A proper allocation of responsibility between sellers and consumers to prevent misestimations of product risk is likely to occur automatically in markets where sellers are concerned about developing and maintaining goodwill, and where consumers can easily discover hidden costs after they have purchased the product. Under those circumstances it is simply unnecessary for government to intervene to protect consumers. By contrast, intervention may be appropriate when sellers are unconcerned about goodwill or when hidden costs can be passed on to an unsuspecting public with no detrimental effect on goodwill.

Consumers are often willing to pay a premium for trustworthiness and the chance to avoid costly diagnosis, testing, and searching among unknown products.[81] For the seller who capitalizes on it, this willingness to pay more for a trusted product can ensure a stable or growing market. To preserve his market, however, the seller will have to incur costs of maintaining product quality and consumer satisfaction. At the least, he must inform consumers of potential hidden costs, when it is more efficient for him than for the consumer to discover and draw attention to them, so that consumers can make informed trade-offs between quality and price.

Such a private ordering of responsibility cannot be presumed, however, when sellers have no particular stake in maintaining goodwill. Indeed, under these circumstances, it may be in their interests to mislead consumers, to fail to disclose hidden costs, or generally to sell products that fail to meet consumer expectations. And it is here that government intervention *may* be appropriate.

Sellers are apt to be unconcerned about goodwill when consumers' surprise and disappointment at the product's hidden costs have no bearing upon future sales. This is likely to occur if 1) consumers do not know of the existence of these costs; 2) consumers know of their existence, but are unable to attribute their cause to the particular product or seller; 3) the seller is not dependent on repeat purchases or "word of mouth" reputation; or 4) the seller, because of market power or collusion with other sellers, knows that the consumer has no real choice as to source of supply.

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[81] *See* text following note 78 *supra*.

A. *Difficulty in Detecting Hidden Costs*

There are some products whose hidden costs may easily go undiscovered. High energy costs due to faulty installation of home insulation, or poor-quality insulation, are difficult for the average consumer to detect, since the monthly utility bill provides no easy method of calculation. Manufacturers and sellers of insulation therefore have little incentive to test their product's energy-saving potential or to provide consumers with truthful information. Similarly, poor nursing-home services may be difficult for the purchaser to discern, because the purchaser is often not the elderly beneficiary. Moreover, the patient is often too enfeebled to judge or complain about the quality of care. Accordingly, nursing-home operators may have little incentive to maintain adequate quality control, or truthfully to inform prospective purchasers and patients of the level of service provided.

Ignorance of hidden costs also underlies consumer dissatisfaction with what is suspected to be unnecessary work performed by auto mechanics or doctors. If diagnostic or testing information is sold in conjunction with the service, the consumer may be unable to judge the accuracy of the diagnosis or the necessity of the operation or repair work. But, because it is normally more efficient to bundle diagnosis and treatment together rather than require that the mechanic or doctor put the subject back together between diagnosis and treatment, the consumer often is reluctant to undertake the extra expense of separating them and getting a "second opinion." The consumer can assess whether such unbundling is worthwhile only if he is aware of the risk and cost of the bundled as against the unbundled diagnosis and treatment—risks and costs which the seller often has no interest in disclosing.[82]

B. *Difficulty in Attributing the Cause of Hidden Costs*

Many products have hidden costs which are not readily traceable because the costs appear at such time or in such form that their magnitude or cause cannot be discerned. For example, carcinogenic properties of certain food additives, drugs, or cosmetics may not become apparent for years after use, and even then it may be difficult to attribute the problem to particular products. Hence, manufacturers and retailers will have little incentive, notwithstanding their interest in maintaining goodwill, to test for carcinogeneity. Indeed, if consumers cannot know of a product's carcinogeneity, manufacturers and sellers may have little incentive to develop safer products. The cost of research and development is not likely to be offset by increased sales, since skeptical consumers will probably discount advertisements of non-carcinogeneity, knowing they will never be able to verify them.

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[82] One particularly tragic example of risky and costly bundling recently came to light in Japan, where physicians are permitted to sell drugs directly to patients on their own prescriptions. The drug Clioquinol, used throughout the world since 1899 in antidiarrhea medicines, has been found to cause a severe and crippling nervous disorder when ingested in large quantities. Only in Japan has the drug had these widespread harmful effects, because Japanese doctors have prescribed larger daily doses for longer periods than physicians in any other country. This might be explained by the bundling of diagnosis, prescription, and retail sales, which gives Japanese physicians a strong financial incentive to over-prescribe. *See* Wash. Post, Mar. 18, 1979, § A, at 1, col. 5.

Sometimes hidden costs can be traced to particular products, but the products themselves cannot be attributed to particular manufacturers or sellers. The identification of a defective product with its manufacturer becomes difficult if the manufacturer frequently changes models or promotes a new image, as is often the case with automobiles and household products, respectively. And, even if identification is possible, the past disappointment of consumers may be overborne by promises of new and improved products. Alternatively, if the manufacturer fears that consumer dissatisfaction with one of its brands will jeopardize others, the manufacturer may attempt to conceal its corporate identity and induce the consumer to believe that there is no connection between brands. For example, corporate sellers frequently hide their identity when they sell "seconds" at lower quality and lower price than their name-brand goods.

When consumers are unaware of hidden costs or cannot attribute their cause to a particular product or seller, they are unable to act on their dissatisfactions. They cannot alter their own buying behavior or that of their friends and neighbors, because they do not know what needs to be altered. As a result, seller goodwill is not in jeopardy and sellers have no incentive to remedy the problems. This suggests that government intervention may be appropriate. It also suggests that consumer complaints are poor indicia of which markets are most in need of government intervention; the complaints themselves are evidence that consumers are able to discover the causes of their dissatisfaction, an important first step in eliciting a market response.

C. *Non-repeat Sales*

If the seller is not particularly concerned about repeat purchases by the same consumer or other consumers within the same geographic area, then he has no goodwill incentive to discover and communicate hidden costs. So-called "fly-by-night" sellers, moving rapidly from city to city; mail-order houses, telephone solicitors, and door-to-door sales networks that rely upon ever-new geographic markets; and sellers of "once in a lifetime" products, such as exotic vacations or tracts of land, often do not depend on repeat purchases.[83] Because consumers and their neighbors rarely have prior experience with these sellers, the latter reap no particular benefit from a reputation for trustworthiness. Rather than invest in building such a reputation by ensuring that consumers get the value of their bargain, it is often more profitable for such sellers to invest in ways of overcoming the reluctance of consumers to contract with the unknown. For example, the seller may offer a discount. Or, frequently, the seller will provide large commissions to its sales force, a guarantee of aggressive, if not ruthless sales practices.

D. *Low Level of Competition*

The value to the seller of goodwill is intimately related to the competitive structure of the market. Sellers may have an incentive to warn consumers of hidden costs in their competitors' products if their own hidden costs are lower, and thereby to build up their own goodwill. But the cost of developing and communicating such information may be greater than revenues expected from increased sales. This may be particularly true if the seller's product has similar defects and the warning merely induces consumers to shift to other product lines, or if the product is so similar to others that any newly won sales will be widely shared. But, even if it were profitable in the short run to communicate such information, competitors might be unwilling to do so for fear of triggering competition in an oligopolistic market, or of creating opportunities for entry or expansion of sales by new entrants.[84]

More fundamentally, if there is tacit or explicit collusion among sellers, or excessive concentration, goodwill may cease to be an important factor, since patronage can often be guaranteed without it. Under these circumstances, the seller has no particular reason to worry when consumers underestimate the hidden costs of his products. Nor will he have any particular incentive to reduce these costs. He can reap the fruits of his monopoly either by raising prices or reducing quality control, and is free to choose the latter out of sheer laziness. The owner of a so-called "company store" or ghetto supermarket, often a local monopoly, is apt to be less concerned about fulfilling his customers' expectations than he would be in a more competitive situation. Lack of competition may also explain the frustration consumers experience at the hands of indifferent government bureaucrats and unhelpful employees of public utilities. To be sure, in some cartels, non-price competition may substitute for more readily policed price competition, and sellers may invest in means of enhancing their goodwill at the expense of their cartel compatriots. But, the mutual interests of cartel members will not be served if these campaigns degenerate into "octane wars" or "tar and nicotine derbies."[85] There are therefore strong disincentives for investment in goodwill in markets with low levels of competition.

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[83] Mail order companies continue to generate a high number of consumer complaints. Over 15% of the complaints received by offices of the Better Business Bureau in 1978 involved mail-order purchases; door-to-door sales followed closely behind. *See* STATISTICAL SUMMARY OF BETTER BUSINESS BUREAU ACTIVITY (1978).

[84] *See* Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 664-66 (1977).

These four factors—detectability, traceability, reliance on repetitive sales, and level of market competition—often interact. Thus, the likelihood that purchasers of new automobiles will underestimate the frequency and cost of repairs resulting from "piston scuffing" and will not be warned by sellers of this potential "defect" is high because 1) it may be difficult for consumers to detect this problem; 2) it is often difficult to attribute subsequent breakdowns to this factor rather than poor servicing; 3) most consumers are relatively inexperienced in purchasing automobiles, and dealers and manufacturers, although eager for repeat purchases, nevertheless have steady streams of first-time customers and of new lines and models for which they can claim superiority over all former ones; and 4) the industry is highly concentrated, offering consumers a relatively narrow range of real options, all of which are apt to have repair problems of one sort or another.[86]

This is not to say that government intervention is necessarily appropriate whenever one or more factors are present. It may be less costly for consumers to discover and repair a "defect" when it occurs than it is for manufacturers or dealers to warn all purchasers of its likelihood, to repair it free of charge, or to improve the manufacturing process so that such "defects" do not occur. The point is that the proper allocation of responsibility for consumer misestimations is less likely to occur automatically through market forces when there are greater difficulties in cost detection and attribution, less dependence on repeat purchases, or higher levels of monopoly power and collusion. Where such impediments exist, one cannot presume a proper allocation of responsibility to avoid misestimations of risk. Government policymakers may therefore justifiably attempt to balance the costs of intervention against the benefits to consumers of more fully informed purchasing decisions.

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[85] *Id.* 665.

[86] *See* note 49 *supra*.

The lesson for consumer-protection policy is clear. Whether one is considering a legislative or regulatory solution to a perceived consumer problem, the first step is to ascertain whether and to what extent any one of the four impediments outlined above is present in the product or service market under scrutiny. If the impediments are nominal or non-existent, it can be presumed (absent special instances of consumer incompetence or vulnerability, for which government paternalism may be widely accepted, such as addicts, young children, or cancer victims) that the market is efficiently allocating between consumers and sellers the responsibility for avoiding misestimations. If, however, a substantial impediment blocks the market's natural allocation, it *may* be appropriate for the government to intervene. Whether intervention is, in fact, appropriate, and if so, what form it should take, are questions which can then be answered only by weighing the costs and benefits of government action.

V. How Should Government Intervene?

Consumers need protection not because unsafe or defective products are being sold, but because the market may sometimes shield the seller from responsibility for the consumer's misestimation of product risks. This suggests a general approach to intervention that avoids taking direct control over product quality or seller conduct. Since the problem lies in the ability of sellers in certain markets to dispense with goodwill, the solution will usually be to increase the importance of goodwill to those sellers. Such a strategy would begin by overcoming whichever market factors have made goodwill irrelevant.

This general approach to the method of government intervention is borne out by a cost-benefit analysis that aims for the least costly remedy. The cost of a particular intervention has two components: the cost to the government of enforcement, and the cost to the seller of compliance, some or all of which may be passed on to the consumer in the form of higher prices. Exerting direct control over the quality of products or seller conduct typically entails high enforcement costs. New products and models, new advertising campaigns, and new ingredients, are all introduced into the economy at an overwhelming pace. It is simply not feasible for the government to police any but a small fraction of these initiatives. By contrast, a consumer-protection strategy aimed at creating goodwill incentives would involve smaller enforcement costs because it focuses directly on the market and only indirectly on the product.

Similarly, compliance costs are higher for regulatory measures that directly control product quality and seller conduct than they would be for a strategy of enhancing market incentives. In addition to the cost of filing compliance reports with the government, a program of direct controls inevitably raises the quality, and the price, of some products higher than consumers are willing to pay. The alternative approach outlined here, by contrast, would preserve the efficiency of the market: sellers would invest in goodwill only to the extent that consumers were willing to pay a premium for trustworthiness.

To be sure, there may be some products with substantial hidden costs which society simply does not wish to entrust to the market, regardless of the sellers' concern to maintain goodwill. The likelihood of consumer harm from the sale of certain dangerous drugs, unsafe toys, or virtually worthless real estate may be so great relative to benefits that, nothwithstanding proper motives on the part of sellers, a total ban is justified. Such instances will be rare. By and large, government strategy designed to protect consumers should aim first to foster sellers' stake in goodwill.

How can this stake be enhanced? Possible strategies follow directly from the four impediments to goodwill described in part IV. Consumers' difficulties in discerning the hidden costs of the product, attributing their cause to the product or seller, or discovering the nature of such hidden costs on the basis of previous purchases or local gossip, all correspond to a set of strategies designed to overcome such information impediments. The impediment resulting from low competition levels requires a different set of strategies which bear a curious relationship to the first.

A. *Overcoming Information Impediments*

When manufacturers and dealers are shielded from responsibility because of the difficulty of discerning or attributing to them subsequent hidden costs, consumer-protection strategy should aim to establish causal connections between the product and the subsequent cost. If, for example, the efficacy of a particular home insulation is hard to discern, mandatory disclosures, such as average yearly energy savings, might be appropriate. By the same token, if it is difficult for consumers to attribute unsatisfactory purchases to a large manufacturer or conglomerate whose identity is obscured by a multiplicity of products and subsidiaries, then perhaps the conglomerate should be required to disclose its identity on all its products. And if subsequent health problems cannot readily be traced back to certain drugs, mandatory disclosure of the risks of ingesting the drugs might provide a solution.[87]

Because such cause-and-effect information is apt to be complex, however, consumers often will have difficulty using it effectively. Thus, an appropriate strategy might aim to facilitate independent "information brokers," who can process and simplify the information according to the needs of consumers. For example, manufacturers or sellers of home insulation might be required to offer the services of, or warn consumers of the need for, an energy "auditor" who could independently appraise the home's insulation needs and calculate potential energy savings from various kinds of insulation. Similarly, when diagnosis and treatment are bundled, as with auto mechanics and doctors, an appropriate strategy would be to develop a market of independent diagnosticians who would offer only diagnoses. These individuals would have an incentive to warn consumers of the risk and cost of unnecessary treatment. They might also refer consumers to specialists they knew to be reliable, a role perhaps played in simpler times by family doctors and local garage mechanics. The government may need to subsidize such diagnosticians, however; property rights in the information disbursed by these individuals would be quite limited, rendering their services susceptible to use by "free riders."[88]

When sellers are shielded from responsibility because they are not dependent on repeat purchases by the same consumer or by others within the same locale, methods should be devised to make them accountable for their improprieties. For example, companies that sell by mail-order or from door to door might be required to maintain up-to-date files of consumer complaints and to inform prospective purchasers about the incidence and subjects of consumer dissatisfaction.[89] Alternatively, these companies might be required to maintain broad warranty and insurance coverage. Finally, responsibility might be placed upon a third party who, because it deals repeatedly with the seller, is better able than individual consumers to hold the seller accountable for defective products or poor service. If, for example, consumers were legally entitled to invoke against a creditor who financed their purchase of shoddy merchandise the same claims and defenses they have against the seller, the creditor surely would have a strong incentive to monitor the performance of the sellers with whom it deals. So long as this rule is limited to creditors who have regular business dealings with the seller, it may be a way of maintaining seller accountability far more efficient than setting minimum standards for the purchased goods.[90] A similar remedy would require sellers of products with particularly high hidden costs to sell only through fixed location dealerships or department stores, where reputational stake is likely to be higher than in mail-order or door-to-door sales operations.[91]

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[87] *See* Pitofsky, *Beyond Nader*, *supra* note 84, at 673-75.

[88] *See* text accompanying note 79 *supra*.

[89] For an alternative remedy, see FTC Mail Order Rule, 16 C.F.R. § 435 (1979).

These strategies for overcoming impediments to goodwill may be inadequate or overly cumbersome. Ensuring that particular disclosures are provided, that offers are made of auditors and warranties, or that third parties are adequately policing the transaction can pose a substantial enforcement burden. In seeking to make sellers accountable for the consequences of their sales, it may therefore be more efficient for the government to create and enforce what might be termed "property rights in trustworthiness." Such property rights, which could take the form of licenses or certification, trademarks, or exclusive-sales agreements, would allow higher-quality sellers to differentiate themselves from poorer ones more efficiently than the market would otherwise permit.

Government licensing or certifying can function as an efficient method of quality control when mere reputation cannot. Certain products that have risks difficult for consumers to assess, such as prescription drugs or firearms, are sold only through licensed screeners who can help the consumer to understand the delicate trade-offs involved. Such licensed screeners are well-situated to test products for risks that would elude individual consumers, and can put their knowledge of past consumer product complaints to good advantage in advising on subsequent purchases. Moreover, the licensing or certifying authority can establish minimum professional standards, and can review consumer complaints against licensees in a single revocation hearing. A preferred means of ensuring consumer protection and business investment in the past, licensing today is being considered by several state legislatures for nursing-home operators and other occupations.[92]

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[90] This theory has been embodied recently on a more general level in the FTC's Rule 433. *See* FTC Preservation of Consumers' Claims and Defenses Rule, 16 C.F.R. § 433 (1979).

[91] It is interesting to note in this connection that Montgomery Ward complained to Firestone about the poor quality of its radial tires as early as 1976, two years before the National Highway Transportation Safety Administration ordered a recall. *Product Safety: Tired Out*, NEWSWEEK, Aug. 21, 1978, at 61.

Certification also may foster competition in product quality. If the high cost of credibly communicating distinctions of product quality makes sellers reluctant to inform consumers that the hidden costs of their own are lower than those of their competitors' products, the government can encourage comparisons by developing standardized comparative measures. For example, once the Federal Trade Commission developed a uniform standard for measuring the tar and nicotine content of cigarettes, manufacturers of cigarettes with lower tar and nicotine had an efficient means of communicating their comparative advantage. As a result, manufacturers began to compete vigorously to produce and advertise cigarettes of even lower tar and nicotine content.[93]

Trademarks and brand names can provide sellers an important incentive to establish goodwill and provide an easy means of identifying trustworthiness. Sellers obviously would have little incentive to invest in quality control and promotion if any other seller could capitalize on the investment, and consumers would be unwilling to pay a premium for the quality control and promotional information if they had no way of knowing which product embodied it. Trademark protection makes it profitable for sellers to invest in quality control and promotion to the extent that consumers are willing to pay a premium for them. Consumers profit too, provided that the premium they pay still allows them to save on the total cost of the product, including hidden costs, as well as the costs of diagnosing, searching, and testing it.[94]

Occasionally sellers will contract to transfer their property rights in goodwill to other sellers or several sellers will pool their collective goodwill. These sales agreements can be profitable if the cost to the sellers of maintaining overall quality control, which presumably rises with the number of outlets, is less than the premium that consumers are willing to pay.[95] The Quality Inn trademark, for example, has become for consumers a valuable assurance of quality for which they are willing to pay a premium. So long as that premium exceeds the cost to each independent proprietor of his share of system-wide-promotion and inspection responsibilities, the pooling arrangement will be profitable.[96]

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[92] *See, e.g.*, S. 680, Pa. Gen. Assemb., 163d Sess. (1979), an act providing for licensing of nursing homes.

[93] In 1967, when FTC testing of tar and nicotine content was begun, only 5.5% of the advertising and promotional expenditures of cigarette companies were devoted to cigarettes yielding 15 milligrams or less of tar. 32 Fed. Reg. 11,178 (1967). Ten years later that percentage had jumped to 49.4%. FEDERAL TRADE COMM'N, ANNUAL REPORT TO CONGRESS ON CIGARETTE ADVERTISING, Table 11 (1978). The extent to which public demand for low-tar cigarettes over this period was itself influenced by the ready availability of an easy comparative measure, and how that demand affected advertising and promotion decisions remains undetermined.

The potential to foster competition in product quality may similarly exist for other markets affected by Commission certification efforts. *E.g.*, 16 C.F.R. §§ 259.1-259.2 (1979) (automobile mileage-per-gallon ratings); 16 C.F.R. § 409.1 (1979) (durability and power-consumption ratings for lightbulbs).

[94] *See* text accompanying notes 75-78 *supra*.

Other forms of exclusive dealing arrangements may also serve to ensure manufacturers or sellers that their goodwill remains unimpaired and quality consistently high. Agreements by which dealers provide certain customer services in return for a manufacturer's grant of an exclusive-sales territory can serve as a device for efficient quality control. By this means, manufacturers can prevent injury to their goodwill from careless or shoddy retail servicing, and dealers can capture the benefits flowing from their investment in promoting and servicing a manufacturer's product.[97] Similarly, manufacturers or sellers may limit those permitted either to service their products, or to provide spare or component parts. Such a restriction may ensure that the product will be maintained in good working order and that faulty components will not jeopardize it. Inadequate servicing or faulty components might otherwise undermine a seller's goodwill, particularly if difficulties in attributing the cause of subsequent problems were to lead consumers to lay the blame at the seller's door.[98]

B. *Overcoming Market Concentration and Collusion*

If sellers have little stake in maintaining goodwill because of market concentration or collusion, the obvious consumer-protection strategy would be to foster competition. Such a plan may necessitate a reversal of the strategy of increasing sellers' stake in goodwill by promoting property rights in trustworthiness. Government licensing, trademark and brand-name protection, exclusive-sales agreements, and product tie-ins of servicing or component parts restrain competition by erecting barriers to market entry. All have been the focus of antitrust enforcement.[99] In a market characterized by low levels of competition, therefore, enforcing property rights in trustworthiness may backfire, and reduce sellers' stake in goodwill rather than increase it. On the other hand, if in more competitive markets promotion of property rights in trustworthiness enhances the importance of goodwill, then singleminded pursuit of an antitrust strategy, without regard to its effects on information impediments, will likewise exert a negative effect on consumer interests.

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[95] The premium may rise with the number of outlets since opportunities for consumers to save on the costs of diagnosis, search, and test are increased.

[96] As more hotels qualify for membership, the consumer's premium is likely to grow since the trademark becomes more widely recognized and opportunities for consumers to take advantage of it increase; but the total costs of inspection and promotion also are likely to rise. Theoretically, system-wide expansion should cease when the costs of inspection and promotion reach the highest premium that consumers are willing to spend in return for potential savings.

[97] *See* text accompanying notes 51-58 *supra*.

[98] *See* text accompanying notes 59-60 *supra*.

How then is the choice to be made between those strategies designed to overcome information impediments and those designed to correct competitive impediments? The preceding analysis suggests several rules of thumb.

1. *If products entail substantial hidden costs, attribution and reputation problems make it unlikely that consumers can rely upon seller goodwill, and the market is not particularly concentrated,* the balance may tip toward the creation and enforcement of property rights in trustworthiness. Under these circumstances, tradename promotion, government licensing, exclusive-sales agreements and tying arrangements may be motivated primarily by the desire of sellers and consumers to trade in trustworthiness rather than by sellers' desire to collude. Accordingly, a sensible consumer-protection and competition strategy would foster these property rights. For example, territorial restrictions which encourage dealers to hire well-trained salespersons would be permissible for distribution of complex audio or camera equipment; prospective consumers of these products are likely to want to purchase this extra help in assessing potential hidden costs, and competition in these markets appears to be quite vigorous.[100] By the same token, government licensing of insurance agents, doctors, or auto mechanics is apt to facilitate these sellers' stake in goodwill by overcoming information impediments to a greater extent than it creates competitive impediments. And vigorous promotion of trademarks by hoteliers will probably encourage responsible service in a relatively competitive industry, thereby providing consumers with protection from flea-ridden, sleepless nights.

2. *On the other hand, when a product has substantial hidden costs, but discovery and attribution of these costs after purchase are relatively easy for consumers, and sellers are dependent on repeat*

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[99] *See* text accompanying notes 51-73 *supra.*

[100] *See* Pitofsky, *The* Sylvania *Case, supra* note 54.

sales, there is less justification for territorial restrictions, licensing, trademarks, and tying arrangements. Sellers of home appliances, osteopathy, or haircuts, will in all likelihood disappear from the market with relative dispatch if they fail to satisfy their customers. And this self-corrective feature of the marketplace will be particularly efficient if there are no barriers to entry by potential competitors.

3. *When it is less clear which impediments—information or competition—are paramount,* an intermediate strategy of required disclosures would alert consumers to the quality-control issue, but leave to them the decision whether to invest in trustworthiness. To avoid the anticompetitive effect of a servicing or component tie-in under these circumstances, the seller could be required to disclose to prospective purchasers the existence of the tie-in and the likely future cost, discounted to present value, of the servicing or components. Consumers could then decide if they wished to pay a premium for this guarantee of continued product quality. Similarly, to avoid the anti-competitive effects of government licensing, unlicensed sellers nevertheless might be permitted to sell their products on condition that they disclose the lack of government approval and any pertinent risks that the licensing was designed to address. Consumers could then choose the unapproved, and presumably less expensive product if they wished. Rather than undertake exclusive-sales agreements, manufacturers could allow certain sellers to indicate that they had been inspected and approved by the manufacturer; other sellers would have to disclose that they had not been so approved. Once again, consumers could decide which they preferred.

4. *Finally, when there are little or no hidden costs and products are relatively simple and fungible,* as with laundry detergents, paper napkins, aspirin, liquid bleach, and long grain rice, goodwill is unnecessary to ensure that consumers get what they expect.[101] Under these circumstances the cost of adequate diagnosis, testing, and search is so low that consumers have no need to invest in trustworthiness. Here, vigorous promotion of a trade name may actually cause consumers to overestimate the consequences of their purchasing decision, and to pay a premium for the promoted product upon

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[101] Porter refers to "[g]oods with relatively low unit price, purchased repeatedly, for which the consumer desires an easily accessible outlet"—and for which research costs outweigh the probable gains from asking price and quality comparisons—as "convenience goods." M. PORTER, INTERBRAND CHOICE STRATEGY AND BILATERAL MARKET POWER 24 (1975).

the mistaken assumption that real differences exist among brands. Because trademark or brand-name promotion that artificially differentiates such a product is likely to serve little purpose but to create barriers to competition,[102] an appropriate consumer-protection strategy would be to require the trademark owner to license the trade name to competitors, or to disclose the product's standard "generic" ingredients. Similarly, under these circumstances, government licensing, exclusive-sales agreements, and tying arrangements are unnecessary to present consumer misestimation of hidden costs; they are more apt to protect sellers from potential entrants whose competition might well reduce prices. The best consumer protection strategy would therefore aim at rescinding these property rights. Viewed in this light, the administrative law judge's decision to order trademark licensing in the FTC's *ReaLemon* case seems entirely defensible.

CONCLUSION

This Article proposes a nonpaternalistic rationale for consumer-protection regulation, a rationale superior to that which allows government to intervene whenever it appears to regulators that the benefits of intervention exceed the costs. The critical issue for policymaking turns not on the merits of particular products, but on the characteristics of particular markets. Do sellers have sufficient stake in goodwill to ensure that they will bear the cost of avoiding consumer mistakes, when it is more efficient for sellers than for consumers to do so? When market conditions do not facilitate sellers' stake in goodwill and a substantial likelihood of consumer misestimation exists, government intervention may be appropriate.

This analysis of when government should intervene also suggests how intervention should proceed. Consumer-protection regulation should aim at improving market performance by enhancing sellers' stake in goodwill, rather than improving the quality of particular products or product information. This calls for a strategy combining, in differing proportions according to market characteristics, elements of disclosure, propery rights in trustworthiness, and competition. Such a market-centered approach to consumer protection would require careful analyses of particular industries and sectors, not unlike those that should underlie policy planning for antitrust enforcement. Indeed, data on industry concentration, consumer purchasing patterns, and advertising and marketing should inform decisions to intervene both to protect consumers and to maintain competition. When the two goals conflict, several rules of thumb may help government regulators choose an appropriate strategy to maximize both.

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[102] Studies have shown a strong positive relationship between consumers' perception that unfamiliar brands are risky and the strength of consumers' expressed brand preferences. Other experimental studies have shown that subjects are willing to pay a price premium for brands of bread and beer with which they have experience, even though other brands they could have chosen at less cost were identical in all respects but the labels. For a summary of these and related studies, see Schmalensee, *supra* note 68, at 1036-39.

In sum, regulators engaged in protecting consumers should not act as purchasing agents, substituting their judgments for those of informed consumers. They should instead design ways to encourage the market to provide the quantity and quality of product and information that consumers want. A policy which thus seeks to make the market more responsive to consumer desires need not run afoul of the basic principles of competition policy. Both have at their core the same fundamental purpose: the enhancement of consumer welfare.

THE CONSUMER ADVOCATE
VERSUS
THE CONSUMER

During the last century, recurrent waves of anti-corporate fervor have swept the United States. Although the particular issues debated vary with each era, much of the agitation has focused on allegations of corporate abuse of consumers. Once again, we are riding such a wave, and once again the problem of protecting consumers intrigues us, this time in the movement known as "consumerism."

There can be little doubt that consumerism is an idea of considerable force. For the media, it attracts audiences; for publishers, it is the source of sales; for some manufacturers, it provides a profitable blessing for their wares; and for politicians, it wins votes. That legislators who cast their vote against bills carrying the stamp of consumerism do so at their peril is reflected in the fact that such legislation generally clears Congress by a wide margin. Thus, a bill establishing a Consumer Protection Agency (CPA) passed the Senate in 1970 by a vote of 74 to 4, and a similar bill gained House approval in the current Congress by 300 votes.

One of the distinctive developments during this era's agitation over the consumer has been the birth of the consumer advocate, the self-appointed vigilante of the economic system. Although he is to a large degree indistinguishable from the muckraker of the past, his concept of his role encompasses more than the exposure of corporate malfeasance and extends to active representation—in courts, agencies and legislatures—of his view of the consumer interest.

The central role the consumer advocate plays in consumerism is demonstrated by the proposals for governmental action which have emanated from the movements, in particular the call for the creation of a consumer protection agency empowered to intervene in the proceedings—formal and informal—of virtually all other federal agencies [1] in order to "represent the interests of consumers." [2] This proposal seeks, in short, to institutionalize the consumer advocate as a federal agency and to put the force of government behind the ideology of the movement known as consumerism. As a result, a judgment as to the merits of the proposal

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[1] See generally, U.S. Congress, Senate, *To Establish a Consumer Protection Agency*, Hearings on S. 1177 and H.R. 10835 before the Subcommittee on Executive Reorganization and Government Research of the Committee on Government Operations, 92d Cong., 1st Sess., November 4 & 5, 1971. (Hereafter cited as *Hearings on S. 1177 and H.R. 10835.*)

[2] S. 1177, Sec. 202 (1); H.R. 10835, Sec. 203(b)(1).

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must turn on the validity of the concept of consumer advocacy and of the ideology that spawned it.

I. The Ideology of Consumerism

Defense of the consumer interest is an attractive cause, for all of us are consumers. Indeed, it has long been the creed of those who believe generally in *laissez-faire* that consumer interests should not be subordinated to producer interests, which, when recognized and protected by government, generally lead to monopoly and restriction of output. It is also the case that in an economy heavily dependent on technology and media advertising, problems of the accuracy and availability of information and the safety of products are inevitable. What distinguishes the consumer advocate is his bleak view of the dimensions of those problems and the reasons we face them.

Expositions of consumerism generally begin with a description of the plight of the consumer in the United States today. According to the consumer advocate, the American consumer is in the grip of corporations "able to divert scarce resources to uses that have little human benefit or are positively harmful." [3] Beset on the one hand by products of apparent and advertised safety which in fact endanger his life and limb,[4] the consumer finds on the other that many products are also of considerably less utility than advertising had led him to anticipate.[5] That very same advertising induces him, moreover, through the sophisticated use of applied psychology, to waste his limited funds on items he really does not need.[6]

The consumer's plight is of comparatively recent origin, and stems largely from the complicated technology of today's products. Senator Gaylord Nelson tells us: "Once, the consumer was the final arbitrator in marketplace decisions, but with our society becoming more and more complex, due to increased industrialization and specialization, economic power has shifted gradually away from the American consumer." [7] In other words, the consumer can no longer rely on his sense for adequate information about the safety and usefulness of his purchases, and is at the mercy of Madison Avenue. Manufacturers, moreover, are not generally likely to make the information he desires available lest it hurt their sales.[8]

The list of unsafe, shoddy or unneeded products seems endless. Unsafe automobiles, tires with no durability, flammable fabrics, dangerous or worthless drugs, fraudulent repairs, worthless warranties, leaky pens, adulterated food, bread without nutrition, beef stroganoff with too little beef, superfluous deodorants, and so on, have all received their share of attention. To the consumer advocate these are not isolated instances of human error. To him they are standard operating procedure in the American economy. His estimates of the dollar value of consumer fraud or consumer abuse suggest a problem of enormous dimensions. Thus, Senator Philip Hart's estimate that $200 billion spent by consumers in 1969 (of total expenditures of $780 billion) purchased nothing of value is part of the consumer advocate's stock in trade.[9]

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[3] Ralph Nader, "A Citizen's Guide to the American Economy," *New York Review of Books*, September 2, 1971, p. 14.

[4] *Hearings on S. 1177 and H.R. 10835*, p. 29.

[5] Edward F. Cox et al., *The Nader Report on the Federal Trade Commission* (New York: Grove Press, 1969), pp. 13-33.

[6] Ibid., pp. 18-19.

[7] U.S. Congress, Senate, *Establish a Department of Consumer Affairs*, Hearings on S. 860 and S. 2045 before the Subcommittee on Executive Reorganization of the Committee on Government Operations, 91st Cong., 1st Sess., March 17, 18, 19, 20, 21; April 17, 24; July 15, 1969, p. 4. (Hereafter cited as *Hearings on S. 860 and S. 2045*.)

Why exponents of consumerism insist on attributing the plight of the consumer to recent events is unclear, for the complaints they urge are a cyclical feature of the political landscape.

[8] Cox, *The Nader Report on the Federal Trade Commission*, p. 18.

All of this occurs, we are told, because of the quest for profit.[10] Much, of course, is made of allegations about monopoly and the lack of competition in the economy. But to the consumer advocate it really does not matter whether there is competition or not, because in either case he argues that the consumer is playing a game he cannot win against his corporate adversary. Thus, Mr. Nader tells us there are "thousands of arrangements that make it possible for corporations to avoid competition . . . so that the value of what buyers receive is often outrageously distorted. . . ." [11] On another occasion, however, Nader has found that "company economy . . . is very often . . . the consumer's cost and hazard" and that competition is, "as a result," little more than "racing for the lowest permissible common denominator." [12]

The consumer's plight is not caused by the lack of government agencies. Congressman Benjamin Rosenthal has pointed out that "there are approximately 50 Federal agencies and bureaus performing some 200 or 300 functions affecting the consumer." [13] There are also any number of state and local agencies performing similar consumer protection functions. Thus, it cannot be said that a mindless adherence to *laissez-faire* has left the consumer at the mercy of malevolent producers.

Among the federal agencies directly concerned with consumer affairs, for example, are the following: Federal Trade Commission, Consumer and Marketing Service (Department of Agriculture), Federal Communications Commission, Federal Housing Administration, Federal Power Commission, Food and Drug Administration, Interstate Commerce Commission, National Bureau of Standards, National Commission on Consumer Finance, National Highway Safety Bureau, National Transportation and Safety Board, Office of Consumer Services, the President's Committee on Consumer Interests, and the Securities and Exchange Commission. Indeed, the history of consumerism—consumerism has, after all, been a recurrent theme in American politics for years—is a history of the growth of a large state and federal bureaucracy.

All seem to agree, however, that government regulation has failed. The reasons for this failure are numerous but three recurring ingredients can be identified. The first is sloth, pure and simple. Too many bureaucrats tend not to work a full day or to be as productive as they might. The "Nader Report" on the Federal Trade Commission (FTC) reported one well-paid official literally asleep on the job.[14] Second, appointments to high positions and subsequent policy decisions are all too often based on partisan political considerations rather than on individual merit and in the public interest. Thus, one of the "Nader Reports" indicates that appointments to the Interstate Commerce Commission are generally political plums,[15] and another charges that the location of a Federal Trade Commission office—in Oak Ridge, Tennessee—was solely for political reasons.[16]

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[9] Nader, "A Citizen's Guide to the American Economy," p. 18.

[10] James S. Turner, *The Chemical Feast* (New York: Grossman Publishers, Inc., 1970), pp. 111, 165.

[11] Nader, "A Citizen's Guide to the American Economy," p. 15.

[12] Turner, *The Chemical Feast*, p. vi (Foreword by Ralph Nader). See also Cox, *The Nader Report on the Federal Trade Commission*, pp. 15, 17.

[13] *Hearings on S. 1177 and H.R. 10835*, p. 19.

The third ingredient is more complicated. Over time an agency will tend to respond most favorably to the organized interests which put the most resources into influencing it. The interest of a single consumer in any particular product is likely to be small and organization with other consumers all but impossible. Producers, on the other hand, tend to be better organized as well as more persistent, and, therefore, more able to influence agency action. Thus, it is alleged, regulatory agencies are all too often "captured" by the very interests they are supposed to regulate.[17] To an unknown extent, similar forces also operate in the legislative process. Licensing regulations at the local level are often enacted in the name of the consumer but are in fact the handiwork of the regulated interests, and one revisionist historian has attributed much of the legislation of the Progressive Era to similar pressure from business groups.[18]

II. The Cure Offered by the Consumer Advocate

Having completed his description of the sorry plight of the American consumer, the consumer advocate offers a multitude of remedies, of which only the most important can be described here.

First, better people must be appointed to responsible positions in the regulatory agencies, for, in the consumer advocate's view, it is the quality of the people appointed, rather than the nature of the regulatory mission, which has led to the failure of government. Thus, the "Nader Report" on the FTC said: "The real problem of the FTC—and indeed of any faltering agency—can usually be traced to *people* "[19] (original emphasis).

Second, the rhetoric of the consumer advocate leans toward measures which hinder the marketing of any product deemed "unsafe," with little regard to its potential benefit.[20] Although there is considerable ambiguity as to what disposition should be made of common items like matches and knives, the consumer advocate is prone to subject new products to tests which require that safety be established before marketing, no matter what the potential benefits. The danger of a thalidomide being marketed is to him presumptively greater than the danger of a penicillin being suppressed.[21]

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[14] Cox, *The Nader Report on the Federal Trade Commission*, p. 148.

[15] Robert Fellmeth, *The Interstate Commerce Omission* (New York: Grossman Publishers, Inc., 1970), pp. 1-4.

[16] Cox, *The Nader Report on the Federal Trade Commission*, pp. 137-139.

[17] Fellmeth, *The Interstate Commerce Omission*, pp. 15-22.

[18] Gabriel Kolko, *The Triumph of Conservatism* (Cleveland, Ohio: Quadrangle Books, Inc., 1963).

[19] Cox, *The Nader Report on the Federal Trade Commission*, p. 130.

[20] Turner, *The Chemical Feast*, pp. 98-103.

Third, he would outlaw the marketing of products which fail to meet particular quality standards. Stroganoff without a specified percentage of beef is not stroganoff and should not be called such.[22] It is also a loophole in the law to permit a product which appears to be a salad dressing but does not meet salad dressing standards to be sold as a "whip." [23] And he regrets that "in 1970 this gaping loophole in the law is still substantially available to manufacturers, allowing products such as Gatorade, the 'thirst-quencher,' on the market. Since the law has no standards for 'thirst-quenchers,' Gatorade can legally contain whatever the manufacturer chooses, although now he must list the ingredients on the label." [24] The implication of such an approach is that government is to draw up a list of permissible products with requirements as to standardized structure and content. Anything not on the list cannot be legally purchased.

Fourth, the consumer advocate would regulate advertising. It would not do to argue in detail here what has been adequately disposed of elsewhere,[25] but it is clear that the consumer advocate would impose restrictions which would cause the amount of advertising in the economy to decline sharply. Advertisements which emphasize particular qualities of a product, for example, would have to state that the advertised product was not unique, if in fact competitive products also had those qualities.[26] Positive aspects of a commodity, moreover, could not be highlighted without detailing whatever negative aspects might also exist.[27]

Finally, to put the force of government behind his ideological position, the consumer advocate would establish an agency empowered to intervene in the proceedings of virtually all other federal agencies—including, under the most extreme proposals, even informal proceedings. The role of this consumer protection agency (CPA) would be to "represent the interests of consumers" before those other agencies in the hope that the presence and advocacy of an official consumer representative will offset the influence of other organized interests on regulatory proceedings. As Senator Abraham Ribicoff has said, its function would be "to police the departments and agencies to make sure they are doing their job for the consumer. . . . What we are trying to do is put the 210 million Americans in the same position as the adversary involved who is supplying information to the agency, to have that agency head have the same information from the consumer's advocate." [28] The proposed agency would also have power to receive complaints from consumers and to collect information on consumer matters [29]—and under one version of the proposal it would have subpoena power against "any persons" in the nation.[30]

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[21] Ibid., p. 225.

[22] Ibid., p. 64.

[23] Ibid., p. 129.

[24] Ibid., p. 130.

[25] See generally, Yale Brozen, "The FTC Attack on Advertising," speech before the Indiana Broadcasters Association, March 14, 1972.

[26] *Hearings on S. 860 and S. 2045*, pp. 103-105.

[27] Ibid.

[28] *Hearings on S. 1177 and H.R. 10835*, pp. 2, 43.

III. Is the Ideology of Consumerism Sound?

The initial difficulty with consumerism goes to the validity of its factual premises, namely that consumers are needlessly and willfully abused. Of course there are accidents, difficulties about product information and false advertising in a developed economy. But what is the norm for "too many" accidents, "too little" information or "too much" fraud, and how is that norm derived? Elimination of such evils entails costs, and those costs must be weighed against the anticipated benefits. At common law, for example, the calculus of an "unreasonable risk" entails balancing the likelihood of injury, the seriousness of that injury and the cost of avoidance.[31] So too, the value of information to the consumer must be balanced against the cost of collection and transmittal just as the damage caused by deceptive advertising must be weighed against the cost of suppression. These costs, after all, can be substantial. Outlawing the wheel would no doubt save thousands and thousands of lives but no one seems prepared to take the plunge. Similarly, a penicillin unused because of doubts as to its complete safety imposes costs in the form of opportunities foregone.

Very little of the literature of consumerism even hints that a balancing process is involved, but until consumer advocates face that question directly, the allegations of consumer abuse will remain unproven. However the norm is established—and it probably must be on a product by product, case by case, basis—it *cannot be* no risk of accidents, absolutely total information and completely accurate advertising. To measure performance against such norms is utterly unfair and wholly misleading.

Beyond the tendency of consumer advocates to measure performance against unrealistic norms is the fact that much of the evidence supporting the claims of widespread consumer abuse seems anecdotal and unsystematic. The abuse is assumed to exist and the burden of proving otherwise is put upon those who would dare to deny it, with the strong implication that a denial is evidence of one's indifference to the ills of society. Consumer advocates tend to toss off a lot of quotations and statistics but when one culls "estimates" and polemical arguments from verifiable facts, their work product seems far too thin to be taken seriously as an assessment of a trillion dollar economy.

Skepticism as to the scientific basis of consumerism's factual premises, for example, is not discouraged by the liberality with which Mr. Nader [32] and lesser movers of the cause [33] employ Senator Hart's estimate of $200 billion of consumer abuse. But $200 billion seems substantially in excess of total profits for all business and is almost four times total after-tax corporate profits.[34]

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[29] S. 1177, Secs. 204, 205; H.R. 10835, Secs. 205, 206, 207.

[30] S. 1177, as introduced, Sec. 205(d)(1).

[31] Fowler V. Harper and James Fleming, Jr., *The Law of Torts* (Boston: Little, Brown & Co., 1956), pp. 928-936.

[32] Nader, "A Citizen's Guide to the American Economy."

Skepticism further increases in the face of consumer advocates' failure to fashion a theoretical explanation for the phenomena they describe. Mr. Nader is quite revealing when he says "economists for the most part have failed to . . . show how corporations . . . have been able to divert scarce resources to uses that have little human benefit or are positively harmful." [35] One might as well muse over the failure of scientists to explain why the earth is flat. Will economists ever be able to show that businessmen make money by deliberately failing to satisfy consumers? If consumers desire more safety, more quality and the like, greedy businessmen will find it in their interest to fill those desires and very much to their detriment to willfully ignore them. This is so even in the case of the absolute monopolist. He may have a greater margin to work with than his competitors but he still has little reason to take his "profit" in inefficiency and injuries to others rather than in money. If his product leads to accidents, for example, he will lose both customers and lawsuits. And what about competition? If industries are willfully failing to satisfy consumer tastes, there are vast fortunes to be made simply by producing what consumers actually desire. Consumerism seems to assume, therefore, not that businessmen are greedy, but that they are relatively indifferent to profits.

The lack of a theory to explain the phenomena consumer advocates observe is further demonstrated in the ambiguity they foster as to whether their function is to enlarge the consumer's opportunity to satisfy his tastes or to impose their own tastes on him. When Mr. Nader criticizes the food industry for taking steps to "sharpen and meet superficially consumer tastes at the cost of other critical consumer needs," [36] one may fairly ask whose judgment it is that a taste is "superficial" and whose judgment it is that a "need" is "critical." In the circumstances mentioned it seems rather evident that the judgment in question is solely Mr. Nader's.

This ambiguity as to how the consumer is to be "protected" pervades consumerism. No doubt some consumers are misinformed about the safety of a product and no doubt some products appear to be far safer than they are. No doubt also—as I shall argue later—a considerable amount of government regulation can be justified. But there also should be no doubt that most products are less safe than they might be simply because consumers do not want to cover the necessary extra costs. Both knives and matches can be very dangerous and can be made "safer," but it is rather clear that consumers believe the benefits of greater safety do not outweigh the extra costs. Similarly, there can be little doubt that many consumers fully aware of the risk of, say, convertibles, are quite prepared to bear those risks in exchange for what they regard as countervailing pleasures.

As stated above, a judgment about the reasonableness of a risk entails balancing three factors: the likelihood of harm, the seriousness of that harm, and the value of the interests to be sacrificed to avoid that harm. When a consumer advocate labels a product "unsafe," it is he who is making that balancing judgment, not the consumer.

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[33] Morton Mintz and Jerry S. Cohen, *America, Inc.: Who Owns and Operates the United States* (New York: Dial Press, Inc., 1971), p. 138.

[34] *Statistical Abstract of the United States*, 1971 (Washington: U.S. Government Printing Office, 1971), pp. 459, 472.

[35] Nader, "A Citizen's Guide to the American Economy."

[36] Turner, *The Chemical Feast*, p. v (Foreword by Ralph Nader).

Of course, such judgments depend on the information available, but even here the consumer advocate exaggerates the potentials for improving present performance and substitutes his own views for those of consumers. The ease with which the consumer advocate calls for more "information" belies the complexity of the issue he raises. Much of what is called "information" involves questions of judgment, style and taste. Once we pass matters such as weights and measures, product "information" becomes increasingly subjective. "Experts" frequently disagree as to the validity of particular testing standards and methods, a fact which has made the businessman rather vulnerable to attack. When test results are not released, he can be accused of suppressing information; when they are, the charge of misleading tests can be raised. The gross judgments in which the consumer is most interested, moreover, are anything but objective. Which of a number of items is the "best" is not, after all, what is known in ordinary language as a scientific judgment.

Beyond these problems is a conflict between the goal of accuracy and the goal of communication with the consumer. Accuracy pushes toward highly technical language not easily comprehended by a layman (and, if recent reports are correct, lawyers at the FTC),[37] while the need to communicate calls for ordinary words which often cannot accurately portray the intended meaning. Again the businessman is vulnerable to the attacks of consumer advocates because either choice leaves him open to a charge of misleading the consumer.

Information is also anything but costless and the costs of collection and transmittal must be borne like any added cost. The reliability of product testing depends on the size of the sample and the sophistication of the tests. And, if government regulation is involved, legal advice must generally be purchased. Like safety, then, "adequate" information involves costs as well as benefits and is a relative rather than absolute concept.

It is not at all clear, moreover, that the consumer advocate's craving for unlimited information is shared by the consumer, who must sooner or later bear the cost of collection and transmittal. He must also bear the cost to him in time and effort of absorbing the information, a cost which many consumers may regard as outweighing any potential benefits. Consumers do in fact frequently forego opportunities to learn more about their purchases even when the information is free—reading ingredients, for example—and it seems evident that many prefer lower prices to paying for information. Were this not the case, Consumers Union would be one of the largest organizations in the country and a large number of firms would have entered the field of product testing and information collection. Where there is a demand for information—as on motor vehicles, for example—a glance at a newsstand tends to indicate that it can be purchased. Indeed, if consumers were that anxious for more information, competition would—as it often does—compel manufacturers to supply it in most cases, the most obvious exception being where all competing products have the same negative aspect, such as cigarettes.[38] Even there, however, a demand for information would call forth independent testing agencies. Again, therefore, as in the case of safety, the consumer advocate is seeking to impose something on the consumer that he has chosen not to purchase.

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[37] *The National Observer*, May 6, 1972, p. 12; *The New York Times*, May 17, 1972, p. 23.

The willingness of the consumer advocate to override the tastes of consumers has been demonstrated time and time again. For example, the "Nader Report" on the Food and Drug Administration attacks the producers of white bread in the United States for not making their bread more nutritious. Yet the report also says:

> At one time the battle between makers of white breads and makers of whole wheat and other more nutritious breads was carried into the marketplace. The Ward Baking Company in 1921 . . . produced a highly nutritious nonwhite bread and conducted a vigorous campaign to promote it. However, in 1925 the company ran into economic difficulty and was reorganized. The new owners decided to discontinue the production of the more nutritious bread; white bread meant easier and greater profits.[39]

There is simply no way to analyze cases such as this except as instances in which consumers do not have the "right" tastes, although the consumer advocate continues to direct his fire at the manufacturers for not forcing items on the consumer that he does not want.

Similarly, the standardization of products will prevent consumers from buying items they might desire when such items do not comply with the government's list. Those who like Gatorade, for example, would not, if the "Nader Report" had its way, be permitted to purchase it because it presumably does not meet the standard for a "juice," just as those who would take a risk in order to satisfy some other taste will be prevented from satisfying it by rules which prevent the marketing of goods which seem somehow "unsafe."

The late Frank Knight put it well half a century ago when he wrote,

> A large part of the critic's strictures on the existing system come down to protests against the individual wanting what he wants instead of what is good for him, of which the critic is to be the judge; and the critic does not feel himself called upon even to outline any standards other than his own preferences upon a basis of which judgment is to be passed.[40]

When pressed on this question, the modern consumer advocate turns to a favorite target, advertising, and argues that, after all, most consumer tastes have been created by the deceptive techniques of advertising and are not really to be viewed as the true will of consumers. Even accepting that objection at face value, one may, nevertheless, ask in what area of human activity are judgments free of influence by advertising techniques.

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[38] See *Report of the American Bar Association Commission to Study the Federal Trade Commission* (1969) pp. 107-108. (Separate statement of Richard Posner.)

[39] Turner, *The Chemical Feast*, pp. 111-112.

[40] Frank H. Knight, *Risk, Uncertainty, and Profit* (Boston: Houghton, Mifflin Co., 1921), p. 182.

It is all very well for consumer advocates to attack advertising but they themselves merchandise consumerism in a way that puts Madison Avenue to shame. Their activities seem very much geared to media impact and involve a great deal of sensationalism. Consider also the example of how the typical "Nader Report" is merchandised.[41] On the cover, the name Ralph Nader appears twice and in large print. The name of the actual author appears once and in small print. On the back in large red letters is emblazoned: NADER'S RAIDERS STRIKE AGAIN! Nevertheless, except for the use of his name, there is little indication in these books as to what Mr. Nader had to do with their preparation. Furthermore, during congressional hearings in 1969, a Mr. Fellmeth, who has authored two "Nader Reports," was asked whether the reference "Nader's Raiders" was a fair statement. He answered,

> I don't think so. I think it is very inaccurate for several reasons.
>
> First of all, it is inaccurate because Mr. Nader's involvement is crucial, but is not as extensive as that name would imply. At least we are not investigating for him alone in a direct sense.
>
> Secondly, we are not raiders. That is a very inaccurate name, with an inaccurate connotation.[42]

Maybe so, but when they ran it up the flagpole. . . .

My colleague, Professor Arthur Leff, has quite rightly noted that the purpose of this kind of merchandising is to sell consumerism the way Colonel Sanders sells fried chicken.[43]

The point is simply that one cannot reject the market on the grounds that businessmen are too reliant on advertising, since that is also true of consumer advocates. If we are deceived by advertising, there is no way to judge whether it is business, the consumer advocates, or both, that are deceiving us.

In any event, many of the attacks on advertising are exaggerated because the attackers read every ad literally and needlessly reject any resort to imagery or symbols. For example, splashing Mr. Nader's name over the "reports" is in fact informative to the consumer, both as to the ideological slant and the quality of the books, but it is the very form of merchandising technique the consumer advocate likes to condemn.

Of course advertising is not the source of divine revelation or absolute truth. It is advocacy and well understood to be such by the consumer. Advocacy cannot, however, be suppressed in the name of accuracy without reducing the incentive to advertise and thus depriving society of the valuable functions advertising performs. It enlarges the consumer's choice by enlarging his knowledge and it reduces transaction costs by efficiently bringing buyers and sellers together. It is also a critically important weapon of competition. Thus it has been found that heavy advertising tends to be associated with highly competitive rather than concentrated markets.[44]

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[41] Fellmeth, *The Interstate Commerce Omission.*

[42] *Hearings on S. 860 and S. 2045*, pp. 119-120.

[43] Arthur Allen Leff, Book Review of Green, "The Closed Enterprise System," in *The New York Times Book Review*, April 30, 1972, p. 22.

[44] Lester G. Telser, "Advertising and Competition," *Journal of Political Economy*, vol. 72, no. 6 (1964), p. 537.

and that those who seek to repress advertising are often seeking to repress competition.[45] Product advocacy, therefore, can be suppressed only at a high cost to the consumer.

That consumerism will likely impose costs is not readily admitted by consumer advocates, who for the most part prefer to let the consumer believe that he can get something for nothing. Too often he is left with the view that increasing product testing by 1000 percent, making cars "safe," keeping all drugs off the market until they are absolutely "safe," forcing companies to spend large sums litigating and clearing things with a government bureaucracy and paying for that bureaucracy itself will cost nothing in out-of-pocket cash, increased taxes or foregone benefits. It is hard to think of a claim of commercial advertising more misleading than that proposition.

On one issue, however, few disagree with the consumer advocates. Government regulation has failed, and the inefficiency and "capture" by regulated interests alleged by the "Nader Reports" is generally conceded. Some agencies, like the Federal Trade Commission, have been just generally slothful. The American Bar Association's commission to study the FTC, for example, found one senior staff member who openly admitted that he preferred to hire older men because they have been out in the world and had come to appreciate that they were not going to make much of a mark.[46] Regulatory failure, however, involves more than sins of omission. Even the FTC has approached "effectiveness" in enforcing statutes within its jurisdiction which are designed to protect producers rather than consumers,[47] and the work of the Interstate Commerce Commission (ICC) is a clear instance of government regulation protecting monopoly interests in the economy. Professor George Stigler may thus well say, "It is of regulation that the consumer must beware." [48]

IV. Is the Cure of Consumer Advocacy Worse Than The Disease?

The Priority Areas for Government Regulation. It is not my purpose here to define with precision the proper role of government in consumer protection. Rather, it is to identify those areas in which market failure seems most likely and the case for government regulation most powerful. One of the harmful effects of consumerism has been to divert attention from the real issues of locating market failure—consumer advocates really say it is everywhere—and of determining in what areas the government ought to cease regulation entirely. But for one or two exceptions they always call for more and more regulation.

First, the government ought to impose safety regulations where parties other than the buyer or seller may reasonably be expected to suffer injury. There is no reason why I as a pedestrian must bear the risk undertaken by a car owner who purchases low quality brakes, and it is certainly arguable that my son need not bear the risk of my poor judgment as to the safety of his toys.

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[45] Brozen, "The FTC Attack on Advertising."

[46] *Report of the ABA Commission to Study the Federal Trade Commission*, p. 33.

[47] Ibid., p. 45.

[48] George J. Stigler and Manuel F. Cohen, *Can Regulatory Agencies Protect the Consumer?* (Washington, D. C.: American Enterprise Institute for Public Policy Research, 1971), p. 17.

Second, government must play a role in suppressing false advertising. It ought to enforce legal actions by consumers and product competitors[49]—the latter have a more substantial incentive to bear the costs of litigation—against false advertisers. Some have also argued that it is appropriate for government to establish an agency like the FTC to seek out and suppress false advertising. Professor Yale Brozen has contended that false advertisers are in effect "free riders" profiting from the reputation of advertisers who are truthful.[50] Because a consumer cannot determine truth or falsity from the face of an ad, the existence of some false advertising casts a cloud over all advertising. For this reason, Brozen argues that affirmative government intervention can be justified. This intervention is to be distinguished, however, from the kind of regulation which in effect requires that advertising give up the function of advocacy of the product, for example, by disclaiming uniqueness or publicizing negative aspects. That kind of regulation discourages advertising generally and thus reduces the amount of information available to the consumer as well as the amount of product competition.

Third, the government ought to establish uniform standards where objective rules can be imposed, for instance, weights and measures. Without such standards, information cannot be easily transmitted. Competition here, moreover, may lead to the creation of confusing and deceptive standards which the consumer cannot interpret and competitors cannot combat effectively. Government may similarly compel sellers to inform the buyer through labelling as to matters such as quantity and ingredients according to uniform definitions. Providing such information is relatively costless and, in the absence of government intervention, definitions of measures and ingredients may not be matters of uniform agreement and understanding. Similarly, certain contract language can be given a fixed legal meaning. A seller surely ought to be free to make disclaimers, but there is no reason to permit him to label them a warranty. Establishing uniform measures and definitions is a far cry from standardizing products, an act which is necessarily anti-consumer and anti-innovative.

Fourth, where there is a high risk of serious harm, the government can seek out and provide information to consumers if that information is unlikely to be available to competitors or independent testing organizations. The sanitary conditions in which food is processed are of great importance to the consumer and really cannot be accurately discovered other than through governmental action. As the frequency and seriousness of the risk decline and the availability of information to competitors or testing organizations increases, however, the justification for governmental intervention diminishes.

Fifth, when a product is by its nature either dangerous or addictive and there are no close substitutes—cigarettes are an example—some role of government may be justified in bringing relevant matters to consumers' attention because there is less expectation that competitors will inform consumers about safer alternatives.[51] A limitation to dangerous or addictive products and a strict definition of "close substitutes" seems appropriate because, in all other cases, either competitors or independent consumer information organizations will supply the information desired in timely fashion.

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[49] See particularly Professor Richard Posner's analysis on this point in *Report of the ABA Commission to Study the Federal Trade Commission*, pp. 104-106.

[50] Brozen, "The FTC Attack on Advertising."

The scope of the regulatory areas sketched above can be debated. Some no doubt have more faith in regulation than others. Skepticism as to government's ability to regulate effectively will vary from individual to individual and many will not accept some of the arguments outlined above or believe in some not mentioned.

Several are clear, however. First, the presumption ought to be against governmental intervention in view of its failure in the past. Regulation has been a failure of such dimensions that it should be undertaken only in clear cases of market failure. Second, market failure does not automatically call for regulation. Markets fail in varying degrees and government intervention cannot be justified unless the benefits exceed the costs. Careful scouting of regulatory proposals is particularly necessary since many of the alleged causes of market "imperfections" seem inherent characteristics of government regulation. Critics of the market remind us of the relative lack of power of the individual consumer over market decisions and his difficulty in acquiring information. Less readily do they point out that this is even more the case when the individual faces the regulatory machinery of government. A harmful ICC ruling is usually less well-known and always less avoidable than a poorly made appliance. The clamor for regulation ignores this because it is based on the naive view that "the people" exercise continuing control over government. This is, of course, contrary both to the theory and practice of representative democracy, which provides only for periodic and very general accountability. The device of the independent agency, moreover—the mainstay of regulation—reduces even this limited accountability to the vanishing point. Identification of market failure, alone, therefore, is not justification for governmental intervention; there must be a further showing that regulation will work and that its cost will be less than its benefits. Third, it is clear that we now have too much regulation, a good deal of which harms consumers by protecting monopolistic interests. How can we truly say we care about consumer protection while we permit the ICC to continue to exist?

Consumer protection entails identifying areas of market failure and carefully tailoring the role of government to them. The scattergun, anti-everything approach of the consumer advocates contributes nothing to this difficult task but merely diverts attention from the important issues, including the critical need to eliminate superfluous or harmful regulation.

The Cure For The Failure of Regulation Is Not More Regulation. The entire case for the creation of an independent consumer protection agency "to represent the interests of consumers" in proceedings before federal agencies rests on the proposition that the agencies have failed to fulfill their responsibilities. Calling for the creation of the CPA is an astonishing admission of the egregious failure of consumer protection regulation. But surely the mind boggles at the argument that the failure of regulation in the past calls for imposing yet another bureaucratic overlay If this proposed agency arises from a need, as Senator Ribicoff put it, "to police the departments and agencies," one may justifiably inquire who or what is to "police" it. How soon will it too be hiring only older men who realize that they are not going to make a mark in the world? Why is this agency not as susceptible to "capture" by organized interest groups as other agencies? It is surely as tempting a target and it cannot be divorced from political pressure any more than, say, the Interstate Commerce Commission. Are we, in a generation, to hear a call for yet another agency, this time to "police" the CPA?

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[51] Again see the analysis of Professor Posner in *Report of the ABA Commission to Study the Federal Trade Commission* (1969), pp. 107-108.

The CPA also has the potential of creating a bureaucratic nightmare—particularly if, as is proposed, the CPA must be notified of and have a right to intervene in every action of other agencies, formal or informal, affecting consumers. As the chairman of the Administrative Conference of the United States has stated, every act of every bureaucrat affecting consumers cannot be written down and sent to the CPA without crippling government.[52] Even if such extreme suggestions are rejected, the proposed CPA would still serve to delay and increase the costs of government action.

All of the arguments used to support the creation of a CPA suggest not a new agency but the elimination or reform of an old agency. If the FTC is moribund, a CPA—whose director and deputy director would be appointed in the same manner as the FTC commissioners—is unlikely to bring it to life. It will merely double the cost. Why should the citizens of this country have to pay taxes for a consumer agency to appear before the Interstate Commerce Commission to urge that commission to reach the results a competitive market would reach—that is to say, the very results that would occur if there were neither an ICC nor a consumer agency?

There Cannot Be a Single Consumer Representative. The model on which proposals for a CPA are based is the adversary system of our courts. That model, however, is totally inapplicable to the purposes urged by consumer advocates. The lawyer-client relationship is one of principal and agent in which the principal has continuing power to direct the actions of the agent. A lawyer representing a client also has the duty of absolute and single-minded loyalty to that client and an obligation to make whatever arguments are in his interest. Where the interests of two persons conflict, the lawyer may not seek to represent both in one action.

The proposed CPA is in no way analogous to representation by legal counsel. It is the principal, not the agent. It, and it alone, would decide when and for what reasons to intervene in the proceedings of other agencies. There is, moreover, no single client or interest for the CPA to represent. It is a fundamental principle of economics that individual consumers put different values on particular commodities. People may differ as to how much beef they like in their stroganoff and as to how much they are willing to pay for it. Safety and information are also not costless, and different consumers will have differing tastes as to how much of each of those they wish to purchase. Intervention against a product which the CPA believes to be "unsafe," for example, is solely in the interest of those consumers preferring to purchase more safety and to the detriment of those preferring a cheaper product, albeit one of greater risk. There is no way around the dilemma created by empowering the CPA to "represent" persons with conflicting interests.

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[52] See *Hearings on S. 1177 and H.R. 10835*, pp. 186, 193.

One bill pending in Congress defines "the interests of consumers" in part as "the cost, quality, purity, safety, durability, performance, effectiveness, dependability and availability and adequacy of choice of goods and services offered or furnished to consumers; and the adequacy and accuracy of information relating to consumers goods and services. . . ."[55] Such a definition, however, ignores the fact that all of these things can be traded off against each other. There can be more safety and quality for a higher cost and vice versa, and different consumers will prefer different mixes. The proposed consumer protection agency simply cannot "represent" all consumers on these matters.

The very idea that there is such a thing as a consumer advocate is, therefore, little more than a public relations gimmick. It has, however, fed the erroneous and misleading notion that a government agency can be established to "represent" the interests of consumers. All those consumers who prefer a trade-off between cost, quality, safety, information, and so on, different from that determined as "correct" by the agency will remain unrepresented in all of the proceedings. This is a grave danger because the very existence of the CPA will conceal the fact that large numbers of people—perhaps in most cases the vast majority of consumers—are in effect unrepresented and are actually being injured by an agency acting in their name.

Consumer Advocates Against the Consumer. Even if the CPA does not fall prey to sloth and bureaucratic lassitude, even if it is "effective," that effectiveness will consist in imposing a particular ideology of consumerism upon consumers. To be sure, some consumers may be helped but many others will be hurt.

It should be recognized, moreover, that the ideology of consumerism does not provide protection against "capture" of regulatory agencies by special organized interests or inhibit coalitions with those interests, particularly if consumer advocates seek and obtain further restrictive legislation. Emphasis on safety, the suppression of advertising, and the standardization of products all tend to dampen competition between firms and are frequently anti-innovative and restrictive influences. Standardization, although the least restrictive, is all too close to the ICC's determination of adequacy of service in deciding whether to permit new entrants into the transportation industry. Firms already in the market with established names and established products will have an enormous advantage. They will, moreover, quite likely see the opportunity to take advantage of the work of the CPA in order to suppress competitors by blocking innovations. Just as the FTC has been more vigorous in enforcing "protectionist" statutes than other statutes in its purview, a CPA will find that a coalition with organized interests is the path of least resistance. The very existence of the CPA, moreover, will tend to legitimate action by other agencies which is monopolistic.

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[55] H.R. 10835, Sec. 304(5).

Consider the case of the compact car. Had consumerism been an active governmental force in the 1950s, it is quite plausible to imagine that measures would have been taken to prevent the introduction of such cars into the American market on the grounds that they were not safe. All of the steps necessary could have been accomplished by a CPA in the name of the consumer, with the automobile industry working silently in the background. This is by no means an imaginary horrible, for allegations about small cars continue. Such a step would, of course, bring about the very results deplored by consumer advocates in other circumstances. But the very fact that the CPA had helped to bring about the exclusion of the car would serve to legitimate what was in effect governmental creation of a monopoly.

Finally, the existence of the CPA will unquestionably make consumers relatively poorer. There will of course be the deprivation of income and benefits which will occur because of the massive bureaucratic delays caused by the CPA and because of the tax revenues needed to cover these delays and the cost of the CPA itself. Consumers would almost surely be better off without such regulation and with the money they pay in taxes to buy more safety and information.

Beyond that, the delays in putting products on the market and forcing firms to expend resources on clearing new products with the bureaucracy, the heavy governmental burden on products which do not meet some norm of perfection will inevitably increase the cost of commodities. And this increase in costs—dictated principally by the political views of the consuming middle class—is likely to have its most detrimental impact on the poor, who will get more quality only when they can pay the higher price.

RICHARD P. NIELSEN

Should Executives Be Jailed for Consumer and Employee Health and Safety Violations?

The Consumer Product Safety Commission was established in 1972 to develop mandatory product safety standards and to prohibit the sale of products which do not comply. The Occupational Safety and Health Administration was established in 1973 to develop and enforce worker safety and health regulations. Both agencies were established with the goal of reducing the number of work and product related injuries, sicknesses, and deaths. Much remains to be done. According to the Consumer Product Safety Commission 30,000 people died and 110,000 people received serious injuries from unsafe products in 1976. The Occupational Health and Safety Administration reports that in 1976 4,500 employees died and 1 out of 11 employees received serious injuries from work related causes. [1, 2, 5, 7]

To supplement the work of OSHA, the AFL-CIO has established a Department of Occupational Health and Safety which currently employs ten industrial hygienists who try to help member unions monitor on the job health and safety problems. George H. R. Taylor, Department Director, estimates that 25-30 of these health-engineering technicians will be employed within the next five years. [7] The CPSC receives help from a different source. The CPSC has established a Consumer Deputy program, in which consumer volunteers with no authority, enlisted and trained by staff in CPSC Area Offices, help monitor retailers to detect non-complying products.[2] Health and safety issues are being given greater priority by unions during contract negotiations. Also, many local union and joint management-labor health and safety committees are being established within the work place. [7] Clearly, a variety of legislative and private measures are being used to control product and occupa-

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tional hazards. The question remains as to whether criminal penalties are needed to reinforce these programs.

Within the past fifteen years there have been increasing grounds for holding executives personally responsible for an organization's behavior. Over a decade ago in an electrical price fixing case, middle managers were sent to prison. However, the top executives of the companies involved, General Electric, Westinghouse, and Allis Chambers, were not considered by the Court to be personally criminally liable for the price fixing because it was not demonstrated that they intended to fix prices or that they knew that the middle managers engaged in price fixing. [6] Since that time there have been several successful criminal prosecutions, convictions, jail sentences, and prison terms for executives. For example, an executive at an H. J. Heinz Co. factory in California received a six month suspended sentence for unsanitary food conditions in the factory. A Minnesota judge ordered Lloyd A. Fry Roofing Co. to pick one of its top executives to serve a thirty-day jail term for violating air pollution standards. A top executive of a grain company received a three month prison term for conspiring to cheat foreign customers by short-weighting ship loadings. One hundred and sixty one executives were convicted on antitrust violations in 1977. Five were jailed. This number is up from only one the previous year. Most of the convictions resulted in either fines or suspended sentences. [6, 10]

Among other laws, the Federal Food, Drug, and Cosmetic Act, the Sherman Act, the Federal Water Pollution Control Act, and the Occupational Safety and Health Act all have criminal penalties for responsible top executives. Amendments to these and other laws regularly have lengthened prison term penalties. The Justice Department has increased criminal prosecutions of top executives in recent years and is more often seeking prison term penalties for those who are convicted or who plead guilty or no contest. This phenomenon is not confined to the United States. For example, top executives in France, England, Russia, and China are currently serving prison terms for factory worker accidents. [3, 6, 10]

DEFINING EXECUTIVE RESPONSIBILITY

Controversy surrounds the crucial issue of how top executive responsibility should be defined. In the June 1975 landmark case of United States v. Park, the Supreme Court ruled 6 to 3 that John R.

Park, the president of Acme Markets, was criminally liable for conduct in a business unit far down in the corporate hierarchy. The case had its origins in November 1971 when the FDA found evidence of rodent infestation in the Baltimore food warehouse of Acme. The FDA informed both Park personally and the company. A second investigation a few months later found some improvement, but still unsanitary conditions. The company and Mr. Park were then charged with violation of the Federal Food, Drug, and Cosmetic Act. The company pleaded guilty and Mr. Park pleaded innocent. Mr. Park contended that as President of Acme which had 36,000 employees, 874 grocery stores, and 16 warehouses, he could not personally supervise all activities. A jury found him guilty despite the fact that: (1) Park ordered a line supervisor to obey the FDA order; (2) Park directed another employee to check on the first employee; (3) Park took these actions in good faith; and, (4) Park was unaware that his orders were not being carried out. The Supreme Court upheld the conviction. [3, 4, 8, 10]

The Court held that an executive is responsible if, by virtue of his position in a company, he had a position of authority and responsibility in the situation out of which a prosecution for a violation might arise. Such an interpretation of responsibility dispenses with more traditional criteria of criminal conduct such as knowledge of the crime or intentional criminal activity. Such an interpretation of responsibility comes very close to absolute liability by virtue of position that permits no defense when a violation occurs. However, the Court's interpretation does not go this far. The Court stated that it does not require "that which is objectively impossible." [3, 4, 8, 10]

The principles established in the Park case may, at least in part, have been reversed recently in the 1978 Supreme Court decision in U.S. v. U.S. Gypsum Co. By a 6-2 vote the Court divided the Sherman Act along criminal and civil lines, requiring proof of intent for the former, but only an anticompetitive effect or purpose for the latter. That is, for a criminal conviction the Court required proof that the executive intended to break the law, while for a civil conviction the Court required only an illegal result that might have been caused without the executive intending to cause a violation. The Court stated that it held the more lenient standard for criminal convictions because criminal conviction without proof of intent "holds out the distinct possibility of overdeterrence; salutary and procompetitive conduct lying close to the borderline of impermissible conduct might be shunned by businessmen who choose to be excessively cautious in the face of uncertainty regarding possible exposure to criminal punishment for even a good-faith error of judgment." [9]

EXTENDING THE PARK CASE PRINCIPLES[1]

There is great disagreement about whether the Park principles should be extended to the enforcement of all Federal regulations concerned with consumer and worker safety and health.

Mark Green, consumer advocate and Director of Congress Watch, strongly supports the U.S. v. Park principles and their extension. Green says, "Legislation is necessary because the political reality is such that judges don't want to convict executive criminals."

A spokesman for Senator Kennedy says that Senator Kennedy supports the extension of the Park principles into the criminal code noting, "The current criminal code does not contain adequate provisions for getting at serious executive crimes."

David Ewing, Executive Editor of the *Harvard Business Review* and author of *Freedom Inside The Organization: Bringing Civil Liberties To The Workplace,* disagrees. He argues that the problem of responsibility is a result not so much of the behavior of individual executives who do not fulfill their personal responsibilities as it is with the structure of modern business. Dr. Ewing explains that:

> The big crime is the growth mania found in many businesses. There is too much pressure for profits that cause executives to give orders for both increasing profits and making safe products and working conditions. When both goals can't be reached, many executives are pressured not to want to know about potential dangers.

Dr. Ewing suggests that if the competitive pressure for profits and growth can be reduced, then the problem of unsafe products and working conditions would be reduced more through such structural reform of business than through extension of the Park principles.

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[1] The quotations in this section where the sources are not identified were obtained through telephone interviews while the author was serving as free lance reporter/researcher for *The New York Times*. The quotations are used with permission of *The New York Times*.

Meyer Issenberg, a law professor at the University of California, Berkeley, takes a similar position in stressing the structure of business as a more important cause of consumer and worker injuries and deaths than individual top executive culpability. The analogy Professor Issenberg uses is the driver in a hurry who goes through a yellow light expecting and hoping that there will not be an accident. Professor Issenberg compares this situation to the executive under profit pressure who cuts corners on worker and product safety systems with the expectation and hope that no one will get hurt. Instead of prison sentences he recommends monetary fines and reform of the business system.

David Ruder, Dean of the Northwestern University Law School, also emphasizes the structural problems of business as a cause of problems and adds that:

> The social disgrace of a criminal conviction for a business executive is worse than for a street criminal and that often the executive's health suffers and many executives die from the stress of criminal proceedings. If the penalties for top executives are too harsh, the society may have difficulty finding competent business leaders to take the necessary risks required in business.

This is similar to the position the Supreme Court took in U.S. v. Gypsum. [9]

Ralph Nader rejects the argument that blame should be laid on the structure of business rather than individual executives. He says:

> Those advocating structural reforms *instead* of personal executive criminal penalties are either naive, trying to deceive the public, or wish to make it easier for executives to increase their profits or cover up their crimes. A white collar criminal should be treated just like any other criminal.

While conceding that there are structural problems beyond individual culpability that cause consumers and workers to be injured and killed, Ralph Nader emphasized that little is likely to change very quickly without individual responsibility encouraged through prison terms, executive suspension, and behavioral sanctions such as requiring executives to spend time working at the scene of the crime, such as the factory floor where a death or injury occurred. Nader also advocates a solution that he credits David Ewing with raising in the current debate, that of firmly protecting employees who "blow the whistle" on executive criminals.

Jake Clayman, Director of the Industrial Union Department of the AFL-CIO, agrees that the structure of American business is a large part of the problem, but stresses that:

> Fines don't mean anything to top business executives. While I am not quick to recommend jail sentences for business executives, many workers and consumers are being killed and permanently injured and the Courts have never seriously faced up to executive culpability. Fines don't mean anything. This breeds a kind of feeling that the law isn't applied equally.

In a special report on white collar crime from the Bureau of National Affairs, a legal publishing house, it is similarly observed and documented that Nader and Clayman are correct in noting that many judges have difficulty imposing criminal sanctions on corporate executives except in the most severe cases. However, Norman A. Carlson, former Director of the Bureau of Prisons, points out that criminal penalties even though used sparingly in practice are helpful in compliance and deterence, "Non-prison alternatives don't have nearly the impact of imprisonment."[10] Similarly, *Business Week* observes that the use of criminal penalties even when used infrequently "has succeeded spectacularly at executive consciousness raising". [7] It should also be pointed out though that criminal law is much slower and more expensive to all parties.

The President of one large midwestern manufacturing company, who declining to be identified, agreed with Clayman and stated that:

> Many executives may have to be more concerned with the process and not just the bottom line, but it's not just executives with a lack of social orientation that are the problem. Stockholders want more profits and growth. It's difficult for executives to stand up and talk. Putting a few executives in jail is more treating the symptom than the cause. But now that I think about it, criminal penalties may be necessary until the social orientation problem is solved.

Despite regulatory efforts, thousands of consumers and workers are suffering injury, sickness, and death from product and work related causes every year. The issue of whether and under what circumstances executives should be jailed for organization violations that cause such harm is unlikely to disappear while so many are suffering so seriously.

The relatively short jail terms that the law permits do not appear too harsh relative to the literally thousands of consumers and workers suffering injuries, sickness, and death from unsafe products and working conditions. Criminal penalties do not appear unreasonable, in circumstances where top executives knew that there was a reasonable probability that injuries or deaths could be suffered and did nothing to prevent them; when executives ordered corrections, but did not check to see whether their orders were carried out; or, where top executives permitted an information system to continue even though it did not bring "bad news" about potential injury, sickness, and deaths to their attention.

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VIEWPOINTS AND COMMUNICATIONS

RICHARD P. BEILOCK

The Economics of Jailing Executives for Violations of Health and Safety Regulations

In the preceding issue of this journal, Richard Nielsen dealt with the issue of whether executives should be held criminally liable for health-safety regulation violations.[1] His paper reviewed judicial decisions in this country and offered views, both pro and con. The article deserves much credit for pointing out a serious issue; however, it did not provide a framework for analysis of the problem. It is to this task that this note is addressed.

The analysis will attempt to answer three questions. First, are health-safety regulations necessary? Or, alternatively stated, could not an unregulated market arrive at socially optimal standards of safety?[2] Second, are executives in uniquely influential positions to affect safety levels? Third, if the answer to the second question is in the affirmative, are criminal penalties the socially optimal devices to enforce safety regulations? As a starting point, we will begin with an example of a situation where the unregulated market can lead to socially optimal levels of safety. We will then examine the implications of relaxing the assumptions that were necessary to achieve the optimal solution with a view toward answering our three questions.

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[1] Nielsen, Richard P. "Should Executives Be Jailed for Consumer and Employee Health and Safety Violations?" *Journal of Consumer Affairs*, Vol. 13 (Summer 1979), pp. 128-134.

[2] The socially optimal level of safety will be here defined as that level at which the benefits minus the costs to society as a whole to either increase or decrease safety are negative.

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THE IDEALIZED MARKET SOLUTION

Given the assumptions that all of the costs and benefits of any action are known to all parties, that there are no transactions costs, and that everyone reveals his or her true preferences, the unregulated market can arrive at socially optimal levels of safety. Imagine that a manufacturer has the choice of either building a plant which produces cars with poorly protected gas tanks or of building a plant costing $1,000,000 more which produces cars with better protected gas tanks. Say that 100,000 people each intend to buy one of the cars, and that it would be worth $10.01 to each of them to have a safer car. That is, each would be indifferent between having the safer car, and paying $10.01 less and taking the added risk of the more dangerous car. In this situation, the potential customers would be willing to offer the manufacturer up to $1,001,000 ($10.01 times 100,000 people) to produce the safer car. If they offered him, say, $1,000,500 to build safer cars, then each party, the people and the manufacturer, would be better off by $500. If there were an infinite array of possible plants corresponding to different car safety levels, by repeating the above negotiations, it would be easy to show that that plant which cost exactly $1,001,000 more than our first plant would be built. This would be the socially optimal plant, producing an auto with the socially optimal level of safety.[3]

PROBLEMS WITH APPLYING THE IDEALIZED MARKET SOLUTION

Unfortunately, in the real world, information is not freely and evenly distributed, there are transactions costs, and people are reluctant to reveal their true preferences if they can see some gain from concealment.

Transactions Costs

Loosely speaking, transactions costs may be divided into two parts: the costs of organizing to negotiate and the costs of negotiating. In instances involving health and safety, on one side of the bargaining table is usually a firm and on the other side is a group of workers or consumers or pollution victims. Once both sides are

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[3] If there were n plant designs, each costing $1,001,000 more than the first plant, that plant that could produce cars offering the highest level of safety, ceteris paribus, would be built. That is, only the most efficient plant within each cost range would be considered.

organized, there is no reason to suspect that the costs of negotiating will be higher for one side than the other. However, the costs of organizing and of remaining organized are likely to be far greater for those dealing with the firm than for the firm itself. The firm, almost by definition, is already a cohesive unit with a fairly simple and dispassionate reason for being, namely to make money.[4] On the other hand, a group of consumers or pollution victims are not likely to even know each other. In addition, their goals and expectations are likely to be highly diverse. Even a group of well organized union workers must take into account the often conflicting and emotional wants of various segments of its membership. These factors make it likely that it will be far more difficult for a group seeking higher levels of safety to deal with a firm than for the firm to deal with a group.

To show how this asymmetry in transaction costs can lead to suboptimal safety levels, suppose that the cost of organizing the consumers in the preceding example is $.50 per person, and, again, that all costs and benefits are known. Recall that the manufacturer requires a minimum of $1,000,000 in order to be willing to build the safer car. If the consumers want the safer car, they must pay at least $1,050,000 ($50,000 to organize and $1,000,000 to the manufacturer). Since it is only worth $1,001,000 to the consumers to have the safer car, it will not be worthwhile to seek a safer model. If the manufacturer is unable or unwilling to speculate and build the more expensive plant, the more dangerous car will be produced.

Reluctance to Reveal True Preferences

The reader may be wondering why the manufacturer, in such a situation, would not sell safety coupons, costing $10.01, to the potential customers in order to raise the needed funds to produce the safer car. If each person purchased one coupon, the safer car would be produced, nobody would be worse off, and the manufacturer would make a $1,000 return for his trouble. The problem is that each individual would have an incentive to be a free rider, that is, to not purchase a coupon in the expectation that the coupon purchases of others would be enough to pay for the safer car. Almost 100 people could refuse to purchase a coupon and still the firm would raise the necessary $1,000,000. Everyone would desire to be one of those 100 people.

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[4] For those who wish to argue that firms also maximize sales or executives' prestige or whatever, please keep in mind that the main point here is only that the firm's objective function is likely to be simpler than that of a group of workers or consumers or pollution victims.

Imperfectly Distributed Information

Only in the mind's eye of an economist is all information instantly and costlessly known to everyone. In the real world each one of us is privy to only a small subset of all knowledge. The transfer of information to others involves costs. Moreover, as in the preceding paragraph, there are times when it is advantageous to one party to keep certain information from others. In our example, it is unlikely that the consumers will be aware of the differences in gas tank protection levels between one car and another. It is, however, highly probable that the manufacturer will be aware of these differences. The management, then, has the option of either building the safer car, incurring the costs of informing the public of its cars' superior safety levels, and hoping that the resulting higher price will be sufficient to recoup its costs, or of building the cheaper, more dangerous car and marketing it as though it were perfectly safe. In general, the second choice is the more lucrative. The point is that safety levels are often not readily discernible. A worker may be unaware that he or she is working with radioactive materials; a city might not know that a factory is dumping mercury into its harbor; and consumers may be ignorant to the fact that their cars tend to explode when hit from behind. In each of these instances, however, the management of the firm is likely to have detailed information about the problem and to have an economic incentive to conceal that knowledge.

THE THREE QUESTIONS ANSWERED

We are now ready to apply the results of the above analysis to answering our three questions.

The Need for Health and Safety Standards

In the above analysis it has been demonstrated how the existence of transactions costs, incentives to conceal true preference levels, and imperfect information all conspire to create a situation in which an unregulated market will lead to suboptimal levels of safety. The need for health-safety regulations follows immediately from the preceding statement. Governments exist to provide services to its society that the market is unable or unwilling to deliver, such as national defense. If free markets are unable to provide the level of safety that society desires, it is the duty of government to dictate that that level shall be provided. As a qualifying statement, I should add that merely because the market will fail, does not mean that government will succeed. Certainly anyone who claims that regulations are typically costless and well thought out is either incredibly naive or has a personal stake in a regulatory body. The point here, however, is that if the society is to have optimal levels of safety, some nonmarket solution is needed, namely some form of regulation.

Are Executives Uniquely Able to Determine Safety Levels?

It has been argued that only managements are likely to be privy to relatively complete data regarding the safety levels of its company's working conditions, effluents, and products. Because of this, it follows that executives are the best possible monitors of safety levels. Particularly when one considers the costs and the potentials for loss and/or concealment of attempting to transfer this information to some other body of regulators, the unique position of executives as the ideal regulators becomes clear.

Are Criminal Penalties Appropriate?

Having decided that executives should monitor safety standards, there remains only the task of creating a system of rewards and penalties that will persuade executives to act as if they had society's welfare uppermost in their minds. Since we are assuming that society, via its government, has already dictated its desired safety levels, we are, essentially, attempting to persuade executives not to violate that standard, either actively or passively. But are there not tradeoffs? That is, should not an executive be allowed to sanction some minor erosion of safety levels below the societal standard, if the financial rewards are great? Unless we are prepared to radically alter our view that each individual has an absolute right to his or her own life we must respond to the negative, because a decision to compromise safety standards is, essentially, a decision to kill or injure for profit. Statistical inference, as well as our common sense, tells us that if the probability of an injury occurring is increased and if this increased probability applies to a large number of events, such as 100,000 cars, then there will surely be more injuries. Exactly who or how many will be injured is unknown, but that there will be additional injuries is clear to all but the most sublimely optimistic. Unless we are prepared to instruct executives as to how many dollars they must earn in order to perpetrate assault and/or murder on a roughly specified but anonymous group of individuals, we must conclude that society's chosen level of safety must be strictly adhered to.

The use of the words "assault" and "murder" in the preceding sentence probably surprised most readers, but it is essential to understand that this is precisely what is being discussed. Suppose that both the safer and the less safe car of our example were available, with the safer car selling for $10.00 more. Mr. X chooses to save the $10.00 by purchasing the less safe auto. He is not, by this act, committing suicide for the $10.00. He is simply assuming a slightly higher level of risk. In effect, Mr. X is underwriting himself against a slightly elevated possibility of what is still an unlikely event, i.e., his death or injury due to the weaker gas tank. On the other hand, suppose that Mr. Y decides to manufacture large numbers of the more dangerous car. Since the product defect is not readily discernible, Mr. Y conceals the fact and thereby avoids having to charge a lower price, the wrath of regulatory authorities, or both. The benefit of this action is that Mr. Y will make more of a profit and the cost is that some people will be killed and injured. Unless it is assumed that Mr. Y is extremely naive, it must be assumed that he realizes the existence of this tradeoff. Because Mr. Y will be unlikely to know the victims or to hear their screams does not alter the fact that he is knowingly killing or injuring others for personal gain.

In addition to the moral arguments that murder and assault are criminal offenses, no finite system of monetary fines, as would be levied in civil offenses, would provide the same level of deterrent. Bankruptcy laws impose limits on fines. No person can effectively be charged more than his or her net worth. In addition, most financial losses can be insured against in one way or another. This is particularly true for the well-off and the sophisticated, and executives tend to be both. There are, however, no ways to insure against imprisonment. For all of us time is unidirectional and death is a certainty. Chunks of our lives are priceless in that there exists no market at which we can purchase a replacement. This, then, is the infinite cost that is proper to impose upon executives for the crime of imposing infinite costs on others.[5]

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[5] Some of the individuals quoted in the Nielsen article expressed the concern that making executives criminally liable for safety violations would seriously lower the supply of executive talent. I confess that I fail to understand this argument unless it refers to cases where the executive would be held accountable for infractions that he or she had no knowledge of. If culpability were limited to willful violations, why would a law-abiding executive fear?

APPLYING ECONOMICS TO AN IMPERFECT WORLD

Alfred E. Kahn

For an academician with a practical bent, there is an immense satisfaction in taking principles out of the textbooks and applying them in the real world. That has been my agreeable task as a practitioner of regulation for the past four years.

The economic principles we—my fellow commissioners or board members and I—have been applying are easy to characterize: that economic efficiency requires prices for goods and services to be set equal to their marginal social opportunity costs (that is, the cost to society of the resources that are used to produce additional quantities—resources that will therefore be freed for other uses if and as buyers restrain their demands); and that, whenever it is technologically feasible, competition is the best way to achieve this result, as well as to ensure the optimum rate of innovation and the greatest degree of managerial efficiency—X-efficiency, as economists now put it. What has been especially intriguing about my experience is that it has embraced two quite different regulatory situations—one, the traditional public utilities, where competition seems for the most part not feasible and the economist-regulator is moved to play an active role in trying to produce efficient results; the other, airlines, in which it appears the prime obstacle to efficiency has been regulation itself and the most creative thing a regulator can do is remove his or her body from the market entryway.

But the process of applying these principles—even of simply getting out of the way—

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has been far from simple. The slate on which the economist-regulator writes is all scribbled over with the scratchings of lawyers, jurists, and politicians; the world to which he would apply his principles is excruciatingly imperfect and resistant; and the compass he needs is one that would help him thread his way through the thickets of "second best" (a theory that tells us, in effect, that it may be economically inefficient to price at the "first-best" level of marginal costs in some individual markets if prices in other markets are far above or below that "ideal" level). The really challenging job is deciding not what the ultimate, economically rational equilibrium should look like but what is economically rational in an irrational, "second-best" world, and how best to get from here to there.

Regulating Monopoly

It would be supererogatory for me to linger long over the defects of the institution of regulated monopoly: the sufficient summary is that it combines the worst of both worlds—the evils of monopoly with the stultification of the profit motive. I would add to this the almost irresistible opportunity it offers to use price—typically, very imprecisely and inefficiently—as an instrument for the redistribution of income.

The First Problem: Regulated Monopoly Itself. One of the most sobering lessons of my experience with public utility regulation was the progressive realization that my most energetic initiatives were little more than feeble efforts to compensate for the inherent defects of the institution over which I was presiding.

One of my proudest accomplishments at the New York Public Service Commission was the progress we made in requiring the electric and telephone companies in New York to introduce a system of prices related to marginal costs. For example, the large residential user of electricity on Long Island, instead of paying the previous flat charge of so many cents per kilowatt hour, will soon—if the courts allow—pay rates varying between 2½ cents at night and 30 cents on summer days when the temperature gets above 83 degrees. As a specific example of the encouragement that this kind of pricing will offer to rational choices between consumption and abstinence, energy and insulation, the use of fuels or the sun, consider what the introduction of that marginal cost-based 12-to-1 ratio does to the likelihood of storage cooling being developed and introduced commercially. Again, the business customers of the New York Telephone Company now have to pay for their local calls on a timed basis; they can no longer ignore the fact that additional minutes of conversation have a positive marginal cost. Residential users are offered a similar pricing system, with the inducement of reduced basic charges.

In trying to introduce changes like this we encountered strenuous resistance, not just from large users who thought they would be harmed by them, but from the utility companies themselves. Why? Why would the electric companies cling to a declining block rate structure (whereby the more electricity a customer uses the cheaper each additional "block" of electricity is, without reference to the time of consumption) when it appeared, particularly at times of peak demand, that sales in the final blocks were at prices markedly below marginal cost, and that the result was to intensify the financial squeeze to which the companies were already exposed by the combination of inflation and regulatory lag?

I can think of only two reasons: first, bureaucratic inertia, and second, a lingering assumption that it was in their interest to promote additional sales that require additional investment, in order to build up their rate base. But both of these phenomena are themselves surely the consequence of regulated monopoly—of the absence of competition and of regulation on a cost-plus basis (with allowable returns reckoned on invested capital). So a plausible case can be made that regulation itself was one of the imperfections we were trying to overcome—that all this furious activity to reform utility rate structures was itself necessitated by regulation.

. . . a plausible case can be made that regulation itself was one of the imperfections we were trying to overcome. . . .

This same observation applies, I think, to our strenuous attempts to attack the problem of X-efficiency—our introduction of management efficiency audits, our embodiment of productivity targets in the rates we set, and our efforts to force surprisingly reluctant separate gas and electric companies to integrate their investment and operations more fully. Unregulated monopolists would presumably have strong incentives to hold their costs down and to buy rather than produce for themselves whenever the marginal costs of buying were less than the marginal costs of producing.

A clear understanding of the limits of what regulation can accomplish under monopoly has the very healthy effect of making an economist-regulator anxious to seize every possible opportunity to render regulation unnecessary. We took major steps in New York, for example, toward opening the market for telephone terminal equipment (including interior wiring) to free competition: this particular part of the industry, we were convinced, could be effectively competitive.

The Second Problem: Second Best. Prominent among the opponents of marginal cost pricing of electricity was a group of large industrial and commercial users, some of them opposing it out of ignorance and inertia, others understandably fearing it would be used to discriminate against them, and others simply unwilling to pay the costs of the service they received. They hired a number of economists to proclaim solemnly that it would be inefficient to price electricity at marginal cost—which has almost certainly, after so many years of inflation, come to exceed average revenue requirements, as traditionally determined—when the prices of natural gas and oil are both being held below *their* marginal costs.

The observation was, of course, pertinent. My own provisional answer has the following parts:

(1) First of all, "second best" argues no more persuasively against moving prices to marginal costs than it does against leaving them where they are.

(2) The field price of natural gas is, indeed, being held below marginal opportunity cost; but since, for that very reason, gas is in any event being physically rationed, pricing electricity up to *its* marginal costs is not likely to produce a substantial diversion of consumption to this underpriced substitute.

(3) The price of domestic crude oil, similarly, is clearly being held artificially below the marginal cost to the American economy, which is the delivered price of imports. But the regulation affects only a declining fraction of total domestic supply, and domestic supply is only a part of what goes to determine the retail price.

(4) Moreover, oil is a major input in the generation of electricity (it takes three Btus of oil to produce one of electricity). This fact, along with the external costs (in terms, for example, of our national terms of trade) of sharply rising oil imports, argues powerfully for pricing electricity at marginal cost, at least where oil-fired generation is marginal.

(5) Other less obvious but extremely important substitutes for electricity are all priced at something like their respective marginal costs—insulation, the incorporation of additional efficiency in electric appliances, and equipment. The choice among these particular substitutes cannot be made efficiently unless electricity itself is similarly priced.

In short, the presence of governmentally imposed distortions in other parts of the economy does not, as the opponents of marginalism seem to think, render economic prescriptions invalid. It merely makes the analysis more difficult.

The Third Problem: Subsidization. The same, of course, is true of legislative decisions to subsidize or cross-subsidize certain kinds of consumption. These decisions usually leave a determined regulator a considerable margin of discretion in deciding what shall be subsidized, how much, and how.

For example, Congress is determined to spend as much as $100 million a year of the taxpayers' money to provide air transportation service to relatively small and isolated communities, over relatively thinly traveled routes. There is no point in my fighting that policy, particularly when some case can be made for it on grounds of the external benefits of linking the country together and avoiding urban congestion. But what the Civil Aeronautics Board has done is explain to Congress how it may get what it wants more efficiently, first, by permitting free entry of air taxis and commuter airlines—which can often perform these particular services at much lower cost than the certificated carriers—and, second, by specifying the subsidized services we want to purchase and attempting to purchase them at minimum cost, rather than, as under the present system, essentially by making good the revenue deficiencies of the carriers certificated for this purpose (this description does less than justice to the CAB's progressive efforts over the years to refine the methods of subsidy determination, but it will have to suffice).

Similarly, society seems determined to have basic telephone service provided at less than cost and, even worse from the efficiency standpoint, through internal subsidization. The reasons, when they are articulated at all, are usually stated in terms of externalities (my telephone is valuable to me only as it enables me to reach others) or "social welfare." A regulatory commission can be persuaded, however, (1) that these cases for subsidization apply validly only to the opportunity to *receive* unlimited numbers of calls and, possibly, to place some minimum of outgoing ones, but (2) that they provide very little justification for subsidizing what passes for basic service in most places in the country—which typically includes the opportunity to place an unlimited number of local calls, of unlimited duration, at no extra charge. Confining the subsidy to the former, truly basic service, while introducing individual charges for each additional local call and for additional minutes of calling, minimizes the inefficiency that results from holding rates below marginal costs and has the additional satisfying effect of rewarding with lower bills people who are willing to exercise some restraint in the costs that they impose on the system.

Economic logic can be fruitfully applied also to devising a least-distorting method of financing this internal subsidization. The traditional method has been by charging prices markedly above marginal costs for interstate calls on the ground, among others, that since the very costly installation at the subscriber's end is used for both intrastate and interstate calls, it is only "fair" that both share the responsibility for covering its costs. The consequence is that every time a telephone or a switchboard is installed, some 20 percent of the capital cost is automatically transferred to the interstate revenue requirement, there to be imposed upon long-distance calling.

I can tell you from experience it is possible to persuade regulatory commissioners that it is inefficient to levy the cost associated with these installations on *usage* of any kind—whether interstate or intrastate. The distortion is particularly inefficient in the case of telephony, because it seems clear that the marginal costs of long-distance communications are far below average revenue requirements. And, the Bell System pointed out, this transfer inflated interstate toll charges in 1974 by 40 percent! Since the entire cost is incurred at the time of installation and the marginal cost of *using* the equipment thereafter is zero, we in New York state transferred hundreds of millions of dollars of these annual revenue requirements to the monthly lump-sum charge.

Managing a Transition to Competition

During the last fifteen months, I have been coping with a very different kind of disequilibrium—the transition of the airline industry from a regime of rigid governmental protectionism and cartelization to one of free competition. I have little to add to the extensive literature endorsing that goal. It provides only limited guidance, however, for getting there—specifically, for coping with the inevitable distortions of a transition that is going to take some time, partly because the law under which we operate still requires us to find, case by case, whether granting each application for entry accords with the "public convenience and necessity," while giving each incumbent competitor—exercising procedural rights that trace back at least to the Magna Carta—an opportunity to argue that it will not.

What I propose to explain here is my conversion from a belief that gradualism is desirable to advocacy of something as close to total deregulation as the law will permit, to be achieved as quickly as possible.

My original attitude was based, first, on simple intellectual caution. It was based, second, on a desire not to discredit deregulation by showing an insensitivity to the fears of both Congress and the financial community about what a sudden total immersion in the waters of competition might do to the financial health of the industry, especially since it had just emerged from five or six years of dismal earnings. Finally, I thought that, since the airline companies had lived in a protectionist hothouse for forty years, their managements had to have time to plan for the new competitive era—to rationalize their operations, to meet the additional competition to which they would become subject, and to be ready to grasp the competitive opportunities that would shortly be presented to them.

I was not unaware, even at the outset, of the possible distortions of a gradual process. The theory of second best tells us that if we want to go from point A to point C, it is not necessarily socially efficient to go part way. And I will shortly be presenting several concrete illustrations of the principle. To anticipate the conclusion, however, I originally thought that meant that we ought to move very cautiously, examining the results every step of the way, in hope of minimizing the disruptions and distortions of the transition; my present conviction is that it means we must make the act of faith and move as rapidly as possible all the way to C.

The First Problem: Unequal Competitive Abilities. The airline industry carries over into its present an incredibly complicated burden of restrictions and impediments from the past. The most important explanation of the differences in cost among different carriers is their respective bundles of operating authority and restrictions, and the kinds of routes and route structures they serve—long-haul or short, in thick markets or thin. Moreover, the ability of one carrier to compete successfully over a particular route with another will be heavily influenced by the extent to which it and its rivals have available to them (1) customers from their own feeder routes that they can readily funnel into their own operations and (2) rights to routes going beyond a given city-pair route onto which they can feed their passengers, thereby permitting them to fatten up their flight schedules on routes where there is competition. Continental Airlines, for example, which lacks route authority eastward of Chicago, argues strenuously that it would be at a serious competitive disadvantage if carriers with richly diversified feed into O'Hare Airport from the East were free to invade the comparatively few routes to the West that contribute the bulk of its profits.

Route structure is, indeed, the dominant influence on relative unit costs, but carriers compete over *particular* routes. And while the one with the most feed can flow traffic over particular contested routes and in this way beef up its schedules to the disadvantage of its rivals, there is ample evidence that it is not the biggest carrier, with the most ample "feed" and "beyond" operations, that uniformly enjoys competitive superiority. All three of Continental's competitors between Chicago and Los Angeles, for example, have rich feed from the East; yet Continental competes with them very effectively.

If there are advantages of integration, there are also powerful economies of specialization. A lack of "feed" and "beyond" traffic did not prevent Pacific Southwest from becoming the dominant carrier in the Los Angeles to San Francisco route, or Southwest Airlines from duplicating that success between Dallas and Houston; and, it is interesting to observe, one of Eastern Airlines' most profitable routes is the Washington-New York-Boston shuttle in which it has surrendered any possible advantages of single-plane service, feeder, or "beyond" operations.

So far as I know there is no objective basis for deciding which of these situations is more likely to prove typical—the one in which size and network economies are decisive, or the one in which the specialized carrier will have clear advantages. Most markets undoubtedly fall in between. In market after market today, carriers of widely varying sizes and degrees of integration meet in head-to-head competition; there is no systematic evidence that this cannot continue indefinitely. Perhaps the only conclusion one can and need draw is that, under a competitive regime, these various kinds of market situations will sift themselves out automatically, with various kinds of suppliers emerging successful on the basis of their respective advantages and handicaps in each. Our uncertainty about the outcome of the competitive struggle is no reason to prevent its taking place; the only sensible prescription is to give the com-

Our uncertainty about the outcome of the competitive struggle is no reason to prevent its taking place. . . .

petitors freedom to slough off their artificial handicaps by entering and leaving markets, as they please.

Moreover, if we cannot *predict* how these offsetting advantages and handicaps of the several carriers are likely to work out under a regime of free entry, it seems to me even less likely that we can hope to achieve the most efficient performance of the transportation function by *prescribing* how the thousands of markets should be served, as the proponents of the status quo would have us do. I find it difficult to see how these uncertainties tilt the balance in the direction of a reliance on predictably ignorant regulation in preference to an uncertainly predictable market process.

The Second Problem: Distortions from Moving Piecemeal. Some carriers profess not to worry about their ability to survive a competitive struggle if the CAB were able to deregulate promptly and totally; but they argue strenuously against our decreeing totally free entry into markets on a case-by-case basis, in the order in which applications happen to be presented to us.

The problems they envisage seem to be of two kinds. First, a Continental or a National argues, the market-by-market approach to free entry may subject a carrier to waves of competition in particular markets that are important to it, while it may find itself having to wait a long time for its own turn to come. I see no reason to assume, however, that the order of our proceeding will have a systematic bias of this kind. In fact, our two most dramatic proposals to open large numbers of markets to multiple permissive entry—involving service to and from the underused Chicago Midway and Oakland airports—have been ones in which the great bulk of the traffic will be purely turnaround; in which, therefore, feed and beyond rights will be of little importance; and in which prominent among the applicants are carriers with no such route systems at all.

The second fear is that if only some markets are opened to entry and not others, all the competitive energies of the industry will concentrate on them, resulting in excessive entry and investment. All this comes down to is the destructive competition scarecrow: there seems to be a general belief among defenders of the present regulatory regime that there is something about airplanes that drives businessmen crazy—that once the CAB removes its body from the threshold, they will rush into markets pell-mell, like lemmings, without regard to the size of each, how many sellers it can sustain, and how many others may be entering at the same time. This does not happen in other industries; there is no reason why it need happen in air transport.

. . . there seems to be a general belief among defenders of the present regulatory regime that there is something about airplanes that drives businessmen crazy. . . .

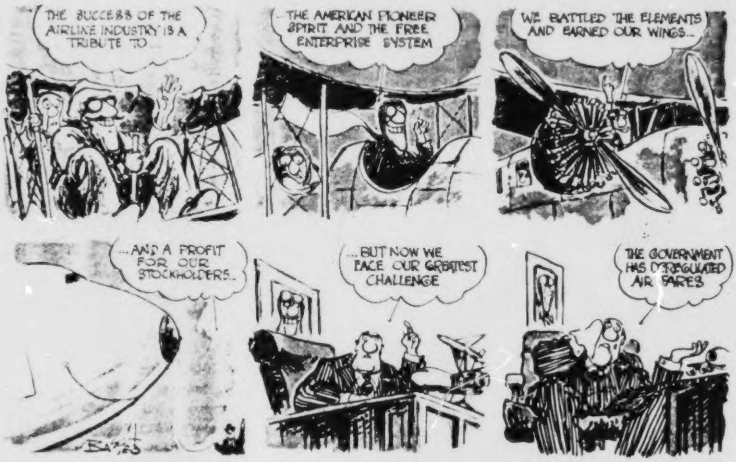
It remains undeniable, however, that the gradual approach, market by market—which may be forced on us by the Federal Aviation Act—must involve distortions. So long as deregulation is incomplete, so long as the certificate of public convenience and necessity continues to have an exclusionary and therefore a market value, some of the airlines assure us, they will apply for more licenses than they can operate economically, and operate under them sufficiently to ensure that they are not taken away; and they will flood markets with more service than is economic in order to preclude competitive operations by others, in the hope of being able in the future to reap the rewards of the monopoly power they achieve and preserve in this way.

The only rational answer is to demonstrate convincingly that the value of these franchises is going to be zero. Then there will be no valuable pieces of paper to fight for with uneconomic operations and no future monopoly gains to offset against the costs of present predation. It is of course necessary to convince the companies that this is going to happen; but the way to do that is to open markets to free entry—and that is what we are doing. Moving as rapidly as possible to a system of universal free entry —and exit—is the way also to deal with the asserted inequality of competitive abilities and opportunities during a slow transition: make the transition rapid; move quickly, on as broad a front as possible, to permit all carriers to slough off the restrictions that limit their operating flexibility, to leave the markets they find it uneconomic to serve, to enter the markets they want to enter. The legal uncertainties are far from negligible; but there is more than a small chance the courts will let us define the "public convenience and necessity" in this intelligent way, provided we explain very clearly to them just exactly what we are doing and why.

The Third Problem: Do Innovators Need Protection? Despite the legend to the contrary, the Civil Aeronautics Board has during its forty-year history admitted a large number of new domestic airlines into scheduled operations; still, the five we have licensed in the past two months to compete directly with the trunks and regional carriers and our adoption both in specific cases and in general principle of the policy of admitting all applicants on a permissive basis clearly reflect a dramatic change in entry policy. (See Chicago-Midway Low Fare Route Proceeding, July 12, 1978, U.S.-Benelux Exemptions, September 1, 1978, and Application of World Airways [Guam Exemptions], September 7, 1973.)

Two of these recent certifications raised the old but still challenging question of the compatibility of pure competition with innovation. These were the extremely attractive novel applications of Midway Airlines and Midway Southwest to provide commuter service between the essentially unused Midway Airport in Chicago and several midwestern cities, at basic fares approximately 50 percent of the level that the CAB had theretofore uniformly prescribed. The first of these was a "paper" company, the second an affiliate of the highly successful Texas intrastate airline that had pioneered in the introduction of the same kind of highly efficient, specialized, low-fare commuter-type service as was being proposed here. The two applications were shortly met with filings by other carriers to serve some or all of the same markets, and with declarations by incumbents already licensed to serve Chicago that they would "meet the competition"—that is, reduce their fares in these markets and in some cases make use of Midway Airport as well—at least one of them before the two new carriers could even hope to obtain CAB certification, let alone acquire the necessary aircraft.

Several civic parties urged us to protect one or both of the innovators by giving them for a year or two the exclusive right to serve Midway Airport; some of them originally pro-


THE SUCCESS OF THE AIRLINE INDUSTRY IS A TRIBUTE TO...
...THE AMERICAN PIONEER SPIRIT AND THE FREE ENTERPRISE SYSTEM
WE BATTLED THE ELEMENTS AND EARNED OUR WINGS...
...AND A PROFIT FOR OUR STOCKHOLDERS...
...BUT NOW WE FACE OUR GREATEST CHALLENGE
THE GOVERNMENT HAS DEREGULATED AIR FARES

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posed that we also prohibit incumbent carriers even from matching the low fares at O'Hare. The innovators, they argued, needed and deserved a period of exclusive right to exploit their new idea. If, instead, we were to permit the many larger and better established rivals to emulate—indeed anticipate—them immediately, how could we be sure, once the two upstarts were aborted or eliminated, that the existing carriers would not drift back to O'Hare, as they had done in the past, each of them finding it in its own interest to concentrate its flights on the airport where its passengers would have the greatest possible likelihood of making connections?

Once again, we confronted the distortions inherent in gradual deregulation. Despite our use of extraordinarily expedited procedures, these applications had been pending for almost two years. In effect, therefore, our certification process was acting like a patent system in reverse: whereas under a patent system, the innovators would have been rewarded for the required public disclosure of their plans with a period of exclusive right to exploit them, under the Federal Aviation Act it would be their already certificated rivals who would be given the head start!

Space will not permit even a summary of the reasons that led us finally to reject this plausible argument. The ultimate consideration was that we were not persuaded it was necessary to grant this period of exclusivity in order to ensure the successful commencement of the service. Instead, therefore, we grasped the opportunity to make our first major grant of universal authority to all applicants, in the belief that this would ensure the fullest and most rapid possible exploitation of the market, and that the competitive market would do a better job than we of deciding what service, and how much, would be economically feasible, and which carriers would be the best equipped to provide it.

But this is not the end of the story. Partly because of the very distortions of the transition that led some of us to think long and hard about giving the innovators a head start, we decided to move even faster and farther than we had originally contemplated. Having decided upon the policy of multiple permissive entry into all the six markets to which we had narrowed the case, in order to make it manageable, we then tentatively decided to extend our permission to an additional seventeen Midway markets by summary procedures (Chicago Midway Expanded Service Proceeding, July 12, 1978). One important consideration was our desire to minimize the undeniable possibility that incumbent carriers would blanket all the available opportunities and so preclude operations by Midway and Midway Southwest. The idea was to open up so many that the incumbents would simply run out of blankets. I was therefore enormously gratified with the reaction to this decision by Midway, which had flatly asserted during the case that it could not get off the ground without exclusive authority. According to the *Wall Street Journal* of July 13, 1976:

> Kenneth Carlson, one of the . . . owners and its marketing vice president, said . . . that by expanding the available routes to 23 from six, the CAB would give Midway Airlines ample market prospects.
>
> "It's going to be harder for [established carriers] to grab us in a bigger fishbowl," Mr. Carlson said.

Precisely as we intended.

The Fourth Problem: Liberalizing Entry When Airport Space Is Inefficiently Rationed. The certification of Colonial Airlines, our third wholly new entrant this year, provides a quite different but even more poignant illustration of the problem of determining what constitutes rationality in an irrational world. Colonial applied for authority to provide commuter service between Morristown Airport, in northern New Jersey, and Washington and Boston. The administrative law judge concluded the service was needed but recommended against certification because Washington National Airport is badly congested at peak hours, its slots are allocated by agreement among the certificated carriers, and there was a real danger that a certificated Colonial, carrying at most fifty-six passengers per flight, would be able to claim a slot at the expense of some other carrier carrying several hundred to or from somewhere else. A rational second-best kind of calculation. In addition, the City of Newark importuned us to turn down the application on the ground that there is excess capacity at Newark Airport nearby.

The basic problem is that airports are for the most part separately owned, that each of them charges landing fees based on its own embedded costs, and that few if any follow peak pricing principles even modestly. So the choices by carriers and passengers of flying times and airports are blithely uninfluenced by what must be vast differences in marginal opportunity costs, except to the extent that rationing by intercarrier agreement produces the same results—which seems extraordinarily unlikely.

We were unwilling to settle for a very poor second best. Therefore we certificated Colonial. In addition, we advised Newark to put pressure on the Port Authority of New York and New Jersey, which operates all three metropolitan airports, to introduce marginal cost pricing—which would mean reducing Newark landing fees sharply and increasing them at the other two; and we began a reconsideration of the antitrust exemption we had been routinely giving the carriers to get together and allocate airport slots. Finally, we initiated consultations with FAA to explore the possibility of devising schemes—preferably rational pricing—to ensure a more efficient allocation of scarce takeoff and landing space. (See Applications of Colonial Airlines, Inc., June 27, 1978, and August 22, 1978.) In this case first best is surely much better than second.

The Fifth Problem: Calibrating the Liberalization of Pricing and Entry. If one is not to remove all controls at once, it is important to try to see to it that controls over price are not removed too fast or too slowly relative to controls over entry. The need for this caution is most obvious in removing price ceilings in the continuing presence of monopoly power.

On the down side, I am not certain that the increasingly permissive attitude that the CAB has taken during the last year toward price reductions—to the point of almost total laissez faire—while new entry by would-be competitors continues to be embroiled in the still maddeningly slow certification process, has not caused us to miss the opportunity for a restructuring of the industry along more competitive lines. It is possible that by permitting incumbent carriers during the last year to introduce a vast variety of discount fares—many of them highly discriminatory and appealing to the same elastic-demand travelers as do the charters and Freddie Lakers—we may have enabled them to foreclose entry into the provision of uniformly low-fare scheduled service by the supplemental carriers, some of whom have been seeking this authority for years.

The final returns are not in on whether we have moved too quickly, although I believe we have not. The pertinent observation, in any event, is that the logic of events has driven us in the direction of trying to synchronize the processes of decontrolling price and entry by speeding up the latter rather than moderating the former—in the direction, once again, of speeding up the transition. Equalizing restrictions turns out to be like equalizing the two sides of a mustache: one can do it much more rapidly by cutting down on the longer side than by extending the shorter one!

Equalizing restrictions turns out to be like equalizing the two sides of a mustache: one can do it much more rapidly by cutting down on the longer side than by extending the shorter one!

The Sixth Problem: Maintaining an Efficient Balance of Price and Nonprice Competition. It would have been equally undesirable to have liberalized entry more rapidly than pricing.

When I came to the CAB it had pending before it over 600 applications for route authority, of varying degrees of vitality and sincerity. Only a handful of these involved a direct promise of price competition—a small hand with only a few fingers. The others were simply applications to enter given city-pair markets and offer service in competition with a single carrier or very small number of incumbent carriers at the same prices.

One lesson we have learned from the history of airlines is that in the absence of price competition, rivalry among carriers tends to take the form of costly improvements in service, particularly additional scheduling. An increase in the number of carriers in a particular market seems to have been correlated with a decline in load factors—an increase, in other words, in cost-inflating scheduling rivalry—producing an apparently self-justifying equilibrium of high fares, low load factors, and consequently high unit costs. This is not to deprecate the value of service competition. The difficulty is that if passengers are presented with no alternative, higher load factor/lower fare offerings, there is not an effective market determination of whether the service offered is too good.

The complete regulator reacts to this dilemma by extending the regulatory net wider, in order to limit these kinds of competition as well—limiting advertising, controlling scheduling and travel agents' commissions, specifying the sizes of sandwiches and seats and the charge for inflight movies. The regulatory rule is: each time the dyke springs a leak, plug it with one of your fingers; just as a dynamic industry will perpetually find ways of opening new holes in the dyke, so an ingenious regulator will never run out of regulatory fingers.

The efficient way to reverse the process of cost-inflating nonprice rivalry is of course to structure markets competitively and permit suppliers to vie for customers by reducing their prices. The consequence will be to raise break-even load factors and, our experience demonstrates, realized load factors as well.

The upshot of these considerations, as of the others, was therefore a decision on our part to press forward on both fronts as rapidly as possible—relaxing our previously rigid controls on competition in basic fares, while trying to open up entry rapidly enough to give new, price-competing carriers a fair chance to survive, and to make it irrational for incumbents to try to forestall them by anticipatory, predatory price cuts. The beneficial consequences are already there, for anyone to see. (The landmark decision, thus far, is Domestic Passenger Fare Level/Fare Structure Policies, September 5, 1978.)

The Seventh Problem: Discriminatory Price Competition. There are three additional observations that I would like to make about the epidemic of special fares—many of them highly discriminatory—that has broken out during our accelerating process of deregulation.

The first is that many of these fares are not discriminatory at all, but represent a logical reflection of the varying costs of the various kinds of service this industry provides or is in a position to provide. The marginal opportunity costs, both short- and long-run, of providing regular coach service—which carries a reasonable probability of a passenger's being able to get a seat on relatively short notice on a conveniently scheduled flight and with no penalty if he fails to show up at flight time—are much higher than the marginal opportunity costs of standby service, or of carrying a passenger who volunteers to be bumped from an overbooked flight, for sufficient compensation (and we will see more of these, under a new board order requiring the carriers to seek volunteers before resorting to involuntary bumping); or of charter service—where the passenger accepts the risk of a heavy penalty if he has to cancel out, and of the flight not going out at all if not enough seats are sold; or of Super-Saver, Budget, or Super-Apex fares, the number of which made available on each flight is restricted to the number of seats the carrier estimates would otherwise go out empty, and which are in principle therefore in effect anticipatory standby fares.

In contrast with ordinary standbys, however, these last fares on scheduled service also embody very substantial elements of discrimination. Many of the restrictions on their availability, such as minimum length-of-stay requirements, are clearly aimed at confining them to demand-elastic customers and have nothing to do with cost. Moreover, particularly when they were first initiated, the fares were extremely discriminatory geographically, being available only on particularly competitive heavily traveled routes. My second observation, however, is that this accentuating price discrimination is symptomatic of the fact that we are still in the transition from tight regulatory cartelization to effective competition: entry is still not free, and until recently the offer of restricted discount fares was the only kind of price competition the CAB was willing to permit.

And this leads to the third point, which is that as the process of deregulation proceeds, much of the discrimination will tend to disappear. There are already signs that this is happening.

Super-Savers, originally available only between New York, Los Angeles and San Francisco, are now available between all major cities in the United States; and Super-Apexes are available from many major cities in this country to many major points in Europe, no longer just between New York and London. Texas International's Peanut-fares, Continental's Chickenfeed, TWA's No Strings and American's Short Stop are available to all comers in the markets in which they are offered, regardless of size, shape, length of stay, or previous condition of servitude: the only control is that—just like interruptible off-peak sales of gas and electricity—the number of discounted seats varies from flight to flight, depending upon their timing relative to the system peak. British Caledonian has divided its planes on transatlantic flights into three compartments, with fares in each based upon its own implicit load factor, and therefore on the degree of comfort and ease of obtaining advance reservations that it affords, and with further differentiations based upon the presence or absence of cancellation penalties, stop-over privileges, and circuitous routings—all of them genuine cost-determining variables.

And, finally, and most satisfying of all, intensifying competition and the removal of CAB prohibitions are at last producing reductions in the basic fares themselves, on a totally nondiscriminatory basis. That process is only just beginning.

Epilogue: Who Bears the Burden of Proof?

One of the most fascinating aspects of the public policy disputations I have participated in during the last four years is the widespread acceptance of the notion that the burden of proof rests always with the advocates of change—that even if one is dealing with manifestly irrational, if not idiotic, arrangements, the advocate of moving in the direction of rationality is called upon to predict exactly how the process will work out and to prove beyond all doubt that it will work perfectly.

The people who think they will be injured by marginal cost pricing of electricity seem to think their intellectual responsibilities are fulfilled by a ritualistic incantation of the two magic words, "second" and "best," although some condescend to enrich the debate further by finding some economists willing to contribute scornful allusions to neoclassical economics.

Similarly in air transport, people who profess to be in favor of freer competition nevertheless demand from the advocates of deregulation guarantees that no town will lose service, even temporarily; that no carrier will be subjected to unequal competitive pressures because it may have inherited a less favorable route structure than its rivals; that there will, furthermore, be no wastage of fuel, no excessive entry into any market, no injurious discrimination, no bankruptcies, no loss of seniority rights anywhere, no danger of increased concentration, and no impairment of scheduled service. Or they will oppose free entry unless and until the advocates can predict in complete detail how the new pattern of operations will look, while professing to be content to leave the fashioning of the future air system, in its every detail, to the very same Civil Aeronautics Board that stoutly asserts its inability to make those predictions.

The opponents and the faint-hearted entreat us to make all our route awards mandatory, exclusive, and rigidly prescribed. The cartelists and protectionists would have us comprehensively prescribe prices, schedules, the size of sandwiches, the pitch of seats, the charge for inflight movies, and travel agents' commissions.

What has been genuinely illuminating to me, in contrast, is how rich a comprehension I have acquired of the distortions of the transition, and how thoroughly I have as a result been converted to the conclusion that the only way to move is fast. The way to minimize the distortions of the transition, I am now thoroughly convinced, is to make the transition as short as possible.

The way to minimize the distortions of the transition, I am now thoroughly convinced, is to make the transition as short as possible.

The ultimate consequence is already clearly in sight. The view is growing more and more widespread among the carriers themselves: if the CAB no longer provides us with any protection at all or if it exposes us to the distortions of gradual and partial deregulation, would we not be better off with no CAB at all? I wish I could say that I had the foresight to have planned it exactly that way! ■

The Mystery of the Dissatisfied Consumer

Complaint letters and opinion surveys only give us clues about why some consumers are unhappy. More information is needed for a good solution.

By George S. Day

FROM Ralph Nader to Virginia Knauer to the forces lobbying for the creation of a new federal consumer protection agency, it has been widely assumed in recent years that American consumers are increasingly dissatisfied and disenchanted with the goods and services of American business — and that this disenchantment is amply justified. A recent survey by the Marketing Science Institute, conducted for Sentry Insurance Company, reported a widespread belief among consumers that the quality of most products is lower than it was 10 years ago.

Even some business leaders have come to accept this litany of the 1970's. "Adverse public opinion," wrote General Motors chairman Thomas Murphy in *Newsweek* last December, "has been shaped to a large degree by the failure of business to satisfy the customer. Much of the public's antipathy toward big business is rooted in the American consumer's own bad experience in the marketplace."

Whether the public's antipathy is justified or not, there seems no doubt that consumers and business people are marching to different drummers these days. Sixty-one percent of a sample of the general public polled by the Marketing Science Institute believed that most products and services have declined in quality in the past ten years, but fully 66 percent of a sample of senior business managers believed products and services have *improved* over the same period. Forty-four percent of the total public sampling believed customers expect less from products today than they did ten years ago; 64 percent of senior business managers felt the customers expect *more*.

Although it's significant that the customers and businessmen have very different perceptions of the consumer satisfaction issue, the question remains: Who is right? Do consumers really feel the way they say they feel? A survey of current methods of evaluating customer attitudes reveals several surprises:

☐ There is remarkably little pertinent data for measuring how happy or unhappy consumers are with the day-to-day performance of business in delivering goods and services.

☐ Consumerist beliefs notwithstanding, most surveys indicate a high level of consumer satisfaction with the majority of products. Unfortunately, there are highly visible exceptions, notably all types of repair services, direct mail, toys, automobiles and some clothing articles. It is these products which contribute disproportionately to a climate of consumer hostility to marketing practices and institutions.

☐ Unhappy though some consumers may be, they rarely complain to manufacturers or even to retailers. Instead they take other actions such as switching brands or retailers. Even if a manufacturer is anxious to please his customers, he may be unable to because there is no easy channel for shoppers to voice their problems to manufacturers.

Both consumerists and business people agree that overall customer dissatisfaction seems to be growing, but they disagree as to why. Consumerists believe that the quality of products is deteriorating, and that this decline is accurately perceived by consumers, whose expectations are reasonably constant. Business people, on the other hand, often say that the performance and quality of products is improving, but consumers' expectations are rising even faster.

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Repair services, direct mail, toys and automobiles contribute disproportionately to consumer hostility.

Both attitudes need to be examined more closely. For example, when consumers contend that business isn't serving them as well as it used to, they may really mean that they are annoyed with contemporary marketing techniques for products and services. As marketing programs are increasingly tailored to specific audiences, people who are not in the intended audience become frustrated or distracted by appeals for products they don't want or can't afford. Ads for furniture and appliances may appeal to newlyweds and ads for Pampers may appeal to new parents, but a great many people exposed to these appeals feel left out and thus develop the notion that business isn't serving them very well.

Finally, if consumers in general are complaining more these days about business in general, is that a reflection on the day-to-day performance of business, or are consumers simply disillusioned lately with *all* institutions?

A more realistic picture of consumer satisfaction comes not from surveys of what people think of business in general, but from reviewing specific experiences of consumers. But even here the message is cloudy. For example, dissatisfaction with a specific product could stem from a variety of factors.

☐ Poor performance of the primary function. Freezers that do not freeze, detergents that can't lift stains and lawnmowers that can't cut grass are serious matters, but they are also rare nowadays — and very obvious.

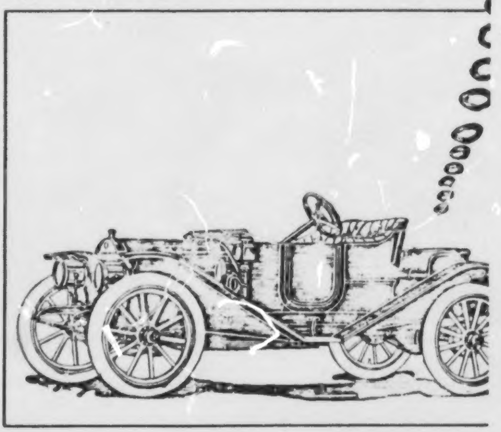
☐ Poor performance of secondary functions. An automobile may perform its primary function — transportation — perfectly, but an accessory, such as the electric windows or the FM radio, may not work. A self-cleaning oven may do a fine job of cooking, but the self-cleaning feature doesn't clean. A new breakfast cereal may be nutritious but may taste terrible. Contrary to most consumers' beliefs, usually the basic product has improved with the passage of time; the "deterioration" perceived by consumers often has to do with the proliferation of new gadgets added to the basic product. A perfectly sound washing machine, for example, may be augmented by timers and controls for rinse cycles, speeds and introduction of softeners and detergents, and each feature has a failure rate of its own.

☐ Disparities between poor expectations and perceived performances. A product may perform both the primary and secondary functions, but not as well as the buyer was led to believe by inflated advertising or sales claims.

☐ Sometimes the product may meet or even exceed expectations, but still the consumer is dissatisfied. If a family could not afford the more powerful floor polisher they felt they needed, they might blame the inadequacies of the one they could afford on the manufacturer rather than on their own limited budget. In other cases, a perfectly good product or service gets low marks from consumers because they would rather not have used the service at all. For example, there are very few happy occupants of nursing homes, but presumably some of these businesses do good work.

☐ Deficiencies compared to alternatives, whether or not the alternatives were available at the time of purchase. A buyer who is perfectly happy with his new stereo system may become dissatisfied with it if he learns, a month or so later, that the manufacturer has produced a similar system under a different brand name, at a much lower price.

ALL these possibilities make it difficult to interpret what a consumer means when he says he's unhappy with a product. If a woman says, "I'm dissatisfied with my refrigerator because it isn't frost-free," she could mean (1) she's sorry she didn't choose a frost-free model when she bought her refrigerator, (2) the newer refrigerators have features that make her model seem obsolete, or (3) de-



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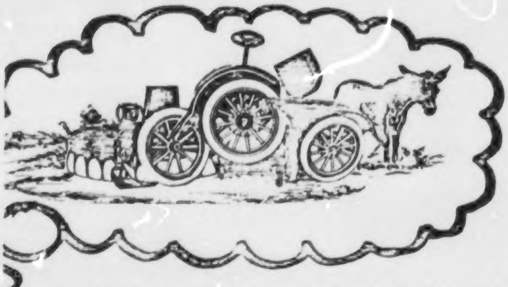

frosting her refrigerator turned out to be more aggravating than she had originally expected. In all three cases, the problem rests with the consumer, not the manufacturer, but the consumer appears dissatisfied.

On the other hand, there are situations where the customer is indeed being abused and doesn't know it – when a service station makes unnecessary repairs to his car, for example, or when food additives cause harmful side effects. It's also difficult for a customer to know whether claims made in a company's advertising are honest or deceptive. Thus, whether a consumer's reactions are favorable or unfavorable, his reactions alone are not necessarily a good reflection of the product's quality.

C F [illegible]

Statistical surveys can be used to measure consumer experiences, but often these surveys raise more questions than they answer – partly because business and government look for different things when conducting such surveys. Business leaders like to express pride in the large *proportion* of customers who are satisfied. Government agencies want to minimize abuses in the marketplace and focus on the large *numbers* of consumers who are aggrieved.

The most thorough example of the "satisfaction-oriented" approach favored by business comes from a continuous customer survey program conducted by General Electric. As of 1972, GE had asked 48,000 customers to describe their "overall satisfaction or dissatisfaction" with some 665,000 individual appliance products, on a five-point scale ranging from "extremely satisfied" to "extremely dissatisfied." According to GE, 94 percent of those questioned were "extremely satisfied" or "somewhat satisfied." To be sure, the proportions varied considerably by product category, age of appliance and so on, but in any case, a 94 percent ratio of satisfied customers does not seem to provide much ammunition for a consumers' revolution. (GE hasn't published the figures from its survey since 1972, but unofficial sources indicate the subsequent proportions have been much the same.)

Similar enthusiastic results were obtained from a 1974 Sears Roebuck mail survey of consumer feelings about 52 categories of general merchandise. Using a three-point scale, Sears found 80.6 percent of its customer sample were "completely satisfied," 16.3 percent were "fairly satisfied," and only 3.1 percent were "not too satisfied" with their most recent purchase. The proportions "completely satisfied" ranged from 94.9 percent for men's dress slacks down to 71.9 percent for pantyhose.

But again, what do the survey results mean? Should we assume that the quality of Sears' men's dress slacks is superior to that of its pantyhose? Or does the survey merely demonstrate that women who buy pantyhose are fussier than men who buy dress slacks? And what are we to make of such maddening terms as "somewhat satisfied" and "fairly satisfied"? After all, a consumer who described himself as "somewhat" or "fairly" satisfied might, upon further questioning, agree that he is also somewhat or fairly *dis*satisfied.

The "problem-oriented" approach favored by government agencies has biases too. Consider a 1975 survey conducted by A.C. Neilsen & Company which mailed a letter to a national cross-section of 1,000 households, asking each to think about problems they had had within the last year with packaged food products and health and beauty aids. After each housewife had time to think about the mailing – and presumably to come up with some dramatic examples of product defects – Neilsen surveyors interviewed each housewife by telephone.

The results? Out of the 1,000 respondents, 330 couldn't recall a single defect and a further 130 reported only package defects. The remaining 540 households, however, reported a total of 1,307 product defects.

In numbers, that is a lot of dissatisfied households, and a lot of product defects. But the number is minuscule when you consider that each household buys hundreds, if not thousands, of packaged food products and health and beauty aids in the course of a year.

On the other hand, precisely because such purchases are so frequent and routine, a housewife isn't likely to remember specific complaints if a Neilsen surveyor calls several months after an unhappy purchase. Let's suppose a housewife buys a package of frozen string beans at her supermarket. She comes home,

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opens the package and finds a dead ant. Horrified, she then returns to the supermarket, chastises the manager and gets a full refund. But a week later she may be back at the same supermarket buying more frozen string beans; and several months later, when the Nielsen surveyors call, she has forgotten the incident altogether.

SINCE neither the satisfaction-oriented approach nor the problem-oriented approach has shed complete light on what marketers should be doing about their products, a consumer-action coalition employed a combination of methods in a 1975 survey. The coalition interviewed 2,419 households by phone, and asked the respondents two questions about their most recent purchase in each of 34 product categories.

Question 1: Was the purchase "satisfactory" or "unsatisfactory" (on a four-point scale)?

Question 2: (A) Those who said they were dissatisfied were asked what the problem was. (B) Those who said they were satisfied were asked whether the purchase could have been better in any way.

Only about 11 percent of all products and 13 percent of all service purchases were said to be "unsatisfactory" or "somewhat unsatisfactory" in response to the first question. However, after further probing with the second question — and especially question 2B — about 28 percent of all purchases were found to be unsatisfactory in some respect. While the second question does help clarify reasons for dissatisfaction, it also plants the seeds of dissatisfaction in people who had thought they were perfectly happy with their purchases. Also, the survey proceeds on the assumption that the customer is always right, when in fact some of the problems perceived by consumers may stem from their own misuse of the products. Finally, because the survey was conducted during a period of high inflation, 25 percent of all reported problems were price related.

Once again, the message of the survey is fuzzy. Nonetheless, even discounting the price related problems, the survey still found that consumers are unhappy with some aspect of 20 percent of their recent purchases. In some categories, such as automobiles and auto repair, the total proportion was more than 30 percent. In the categories of car repair, mail order and home repair, the unhappiness proportion was already about 20 percent before the interviewers asked their prejudicial second question.

Even a conservative interpretation of this data should be troubling to business people. But the question remains: what should they do to make their customers happier? And what is an acceptable standard of product performance? Perhaps both business people and consumerists would agree that a good minimum acceptable standard is continuing improvement — either in the increased proportion of satisfied customers, or in the declining number of dissatisfied customers.

It's worth noting that in the Sears Roebuck study 73 percent of all complaints were registered by only 34 percent of the respondents. By contrast, another group of 32 percent of the respondents reported no complaints with any of their recent purchases in the 34 product categories. The dissatisfaction-prone group may either (1) have higher standards than anyone else, (2) have less tolerance for product shortcomings because of problems in the past, or (3) may be asking for problems by paying lower prices and buying more of their goods at discount outlets. In any case, this group would probably be unhappy regardless of the level of product performance. Surveyors at Sears Roebuck concluded that a level of 85 to 90 percent expressing complete satisfaction is a realistic goal.

The closest most marketers come to explicitly considering consumer satisfaction is a review of complaint letters from customers. Individual complaints are also the primary source of evidence used by consumer-oriented agencies. Complaint letters have an immediacy and directness that cannot be ignored. Someone has taken the time to single out one among the many aggravations and frustrations of daily life, and to express his feelings (albeit in the hope of redressing his grievances).

Complaint letters are also used in providing insights into special problems of

Bringing It Out

In a 1975 survey of 2419 households, consumers expressed dissatisfaction with some aspect of 20 percent of recent purchases, excluding price complaints. When asked further about their purchases, about 28 percent turned out to be unsatisfactory.

Dissatisfied Consumers (%)	1st Question	2nd Question	Total
Car repair	21.5	13.5	35.0
Mail order	19.4	11.7	31.1
Home repair	18.6	9.8	28.4
Car	13.8	18.5	32.3
Grocery items	10.6	15.2	25.8
TV set	9.7	11.1	20.8
Appliance repair	9.6	19.9	29.5
Cosmetics	3.5	5.7	9.2
Credit	6.0	4.6	10.6
Lamps	2.6	5.9	8.5
Average — All Products	9.5	10.5	20.0
Average — All Services	12.0	8.9	20.9

A buyer who is happy with an 8-speaker stereo may become dissatisfied when a 12-speaker model comes on the market.

small groups of consumers who might be overlooked in random test samplings. For example, a new talcum base in a bath powder was tested on a sampling of people and caused no problems. Once it was on the market, though, the manufacturer received dozens of complaint letters from people who were allergic to the new talc base: apparently none of them had been included in the test sampling. Similarly, the development of the safety cap on aspirin bottles – long before the government thought to require it – can be attributed to consumers who wrote letters to drug companies expressing concern about the ease with which children were opening bottles.

Yet complaint letters present a distorted and incomplete picture. People who write such letters are not typical shoppers. They are most likely to be highly educated, articulate and fussy. They may also have more free time on their hands than the typical shopper, who is so busy with job and chores and children that the thought of writing a complaint letter never occurs to him. Most shoppers, rather than demand satisfaction from a company, simply switch brands or shop in a different store. Low-income shoppers are especially unlikely to complain, even when they have strong grounds for complaint, because they don't know how to go about it.

EVEN if an acceptable satisfaction standard could be agreed upon and a method devised to translate customers' complaints into suitable actions, there is no existing method for assuring a free flow of information from consumer to manufacturer, even when the manufacturer is anxious to know what his customers think of his merchandise.

Consider the A.C. Neilsen survey of a thousand households, mentioned above. The survey turned up complaints regarding 1,307 product defects from 540 households. Yet more than 50 percent of those defects were never reported by the housewives either to the retailer or to the manufacturer. In 40 percent of the defect situations the housewife complained to the retailer, who usually mollified her by exchanging the defective merchandise. Only 3 percent of the defects mentioned in the Neilsen survey led to a letter of complaint to the manufacturer. Thus the manufacturers were almost completely cut off from knowledge of consumer unhappiness with product defects, and even the retailers were unaware of most of the problems.

Even less complaining behavior was uncovered in a 1974 telephone survey dealing with the problems of personal care products: 5 percent complained to the manufacturer, 15 percent to the retailer, and the remaining 80 percent took no direct action at all, although 34 percent said they had complained to their friends.

These two surveys, of course, dealt with relatively inexpensive products, and presumably the consumer felt it wasn't worth the time or trouble to voice a complaint to either retailer or manufacturer. At the very least, though, this suggests that the less expensive an item, the less likely is a manufacturer or retailer to know what consumers really think of his products. What is surprising is that even the study by the two consumer action groups, which dealt with a wide array of more expensive products, found that only 31 percent of those consumers with product problems actually voiced a complaint to a manufacturer or retailer. (An additional 1.2 percent did complain to the Better Business Bureau, government agencies, news media or the courts.)

The picture that emerges from these studies suggests a series of obstacles that consumers and manufacturers must hurdle if they sincerely want to communicate with each other. Consumer complaints have a way of being filtered through a chain of command so that the manufacturer is isolated from almost all expressions of woe: only the very largest and loudest complaints get through to him. After all, what motivation is there for the retailer, or the company salesman who calls on the retailer, to report systematically to the head office about complaints and dissatisfaction?

My own informal studies indicate that the head offices of chain stores are almost as isolated from complaints as are the head offices of manufacturers. Many complaints are simply dealt with by the store clerk or the department manager and go no further; they never even come to the attention of the store manager, much less the store's corporate headquarters. And if the store's corporate headquarter is oblivious to complaints out on the front lines, the manufacturer may be even less aware of such problems. Sitting in his office, the most well-meaning of manufacturers may believe that his company is doing a marvelous job of serving the public at the very moment a consumer rebellion is brewing.

There are potential benefits to encouraging more complaints by the use of telephone hotlines, questionnaires inserted in packages and other improved communications devices. But regardless of the effect of such encouragement, it is clear that customer complaints cannot be allowed to serve as the sole source of information about consumer dissatisfaction. ■

Suggested Reading

H. KEITH HUNT, *Ed.*, *"Conceptualization and Measurement of Consumer Satisfaction and Dissatisfaction,"* Marketing Science Institute, *May, 1977. The most comprehensive source of current thinking on the subject of consumer satisfaction.*

LOUIS HARRIS AND ASSOCIATES, INC. AND MARKETING SCIENCE INSTITUTE, *"Consumerism at the Crossroads: A National Opinion Research Survey of Public, Activist, Business and Regulator Attitudes Toward the Consumer Movement," conducted for Sentry Insurance, 1977.*

ARTHUR BEST AND ALAN R. ANDREASEN, *"Talking Back to Business: Voiced and Unvoiced Consumer Complaints,"* Center for Study of Responsive Law, *1976.*

BETTY J. DIENER, *"Information and Redress: Consumer Needs and Company Responses,"* Marketing Science Institute, *June 1975.*

STATE PROTECTION OF THE CONSUMER: INTEGRATION OF CIVIL AND CRIMINAL REMEDIES†

Paula W. Gold * *and Robert D. Cohan* **

State legislation which protects consumers can be found in two major areas: (1) civil statutes specifically enacted to protect consumers, and (2) existing criminal laws. An effective program of enforcement must integrate both. This article will survey the broad range of civil and criminal sanctions currently available to most state enforcement agencies for consumer protection.

The most comprehensive civil statutes for consumer protection are modeled after the Federal Trade Commission Act,[1] which generally prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.

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[1] 15 U.S.C. § 41 *et seq.* (1914).

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Criminal enforcement arises under either traditional criminal statutes, for instance, larceny by false pretenses, or criminal statutes specifically enacted to protect consumers, such as the Model Penal Code sections dealing with unfair and deceptive business practices.

Unfortunately, only a handful of states have developed comprehensive civil and criminal legislative programs designed to protect consumers. Therefore, many state prosecutors are hampered by laws which are inappropriate and unrealistic. Regardless of whether the legislative framework in which the enforcing authority operates is an up-to-date, comprehensive one or a patchwork interrelation of laws, it is essential that the state coordinate civil and criminal remedies to deter unfair and deceptive practices and compensate victims in a timely and efficient manner.

I. Civil Prosecution

Fifty jurisdictions have enacted some form of "baby FTC act."[2] These acts fall into two general categories: (1) those without civil penalties for initial violations which provide only for a penalty in a contempt proceeding for the violation of an injunction, and (2) those which impose either civil penalties and/or criminal sanctions for initial violations.

A. *Statutes Without Civil Penalties for Initial Violations*

Less than half of those states which have enacted consumer protection statutes modeled after the FTC act, including Massachusetts, do not provide for the assessment of civil penalties for initial violations,[3] even though a consumer protection act which provides such penalties is far more effective than one which does not. Although aggressive enforcement of a consumer protection act without civil penalties for initial violations can protect consumers in many areas,[4] states like Massachusetts are hindered in affording full protection to their citizens. None of the available equitable remedies act as a deterrent to those who intend to pursue unfair and deceptive trade practices. A state with a consumer protection act which imposes civil penalties possesses a meaningful deterrent to initial violations of the act.

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[2] Federal Trade Commission Fact Sheet: State Legislation to Combat Unfair Trade Practices, revised October 22, 1976 [hereinafter cited as FTC Fact Sheet]; V.I. CODE tit. 12A § 101 *et seq.*

[3] FTC Fact Sheet, *supra* note 2.

Under the Massachusetts Consumer Protection Act, the Attorney General may seek: (1) an assurance of discontinuance;[5] (2) an injunction restraining the use of unfair or deceptive acts or practices;[6] (3) in the case of corporations which habitually violate injunctions, the dissolution, suspension or forfeiture of the corporation's franchise or its right to do business within the Commonwealth;[7] and (4) restitution for persons who have suffered ascertainable loss.[8] Neither an assurance of discontinuance, nor an injunction, imposes a penalty for the initial violation of the Act; nor does the first violation trigger corporate disenfranchisement. Each remedy seeks to insure *future* compliance. Furthermore, where the assurance of discontinuance or injunction runs against the corporation but does not run against individual corporate officers, the corporate officers can dissolve the corporation and reorganize under a new corporate structure not subject to the assurance of discontinuance or injunction, thereby avoiding the penalties for future violations.[9]

An order of restitution is also of limited effectiveness in deterring initial violations. It is of no value where the operator is judgment-proof as a result of the dissipation of his assets or bankruptcy proceedings; and, even if the operator does have sufficient assets to comply with the order, restitution is only available for those defrauded consumers of whom the state is aware.[10] The operator may retain the remaining illegally gained profits and, at most, is required to return only what he has earned through his unfair and deceptive practices. As a result, the operator may view restitution as simply another cost of doing business, and he will not be deterred from his fraudulent activities.[11]

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[4] *See* Annual Report of the Consumer Protection Division to Attorney General Francis X. Bellotti, 1976.

[5] MASS. GEN. LAWS ch. 93A § 5.

[6] MASS. GEN. LAWS ch. 93A § 4.

[7] MASS. GEN. LAWS ch. 93A § 8.

[8] MASS. GEN. LAWS ch. 93A § 4.

[9] *See* Hearings on S.670, The Consumer Fraud Act, Before the Consumer Protection and Finance Subcommittee of the House Interstate and Foreign Commerce Committee at 3-4 (August 11, 1976) (statement by John M. Nannes, special assistant to the Assistant Attorney General, Antitrust Division); for a discussion of individual liability of corporate officers in Massachusetts, *see generally* 13A Mass. Prac. §§ 643-46.

For the foregoing reasons, the legal effect of a consumer protection act without any fine or penalty for initial violations has been likened to a "dog bite" statute which entitles a dog to one free bite, regardless of the damage caused, before sanctions will be imposed.[12] Fraudulent operators will not be deterred so long as they believe the only sanctions to which they are exposed are restitution and a court order prohibiting a recurrence of the act.

B. *Statutes With Civil Penalties for Initial Violations*

Statutes which impose civil penalties for initial violations provide a significant deterrent to unfair and deceptive acts or practices. Twenty-seven states and the Virgin Islands have enacted such legislation.[13] By eliminating illegal profits through the imposition of appropriate civil penalties, the incentive to *initiate* illegal acts may disappear.[14] Civil penalties may be further justified as punishment for wrongdoing to the victim,[15] society,[16] and also may serve as a source of revenue to help offset the cost of consumer protection to the taxpayer. In addition, because the sanction is civil in nature, practical procedural problems associated with criminal prosecution may be avoided.[17]

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[10] In reference to actions brought by the Attorney General, Mass. Gen. Laws ch. 93A, § 4 states in pertinent part, ". . . [The] court may . . . make such other orders or judgments as may be necessary to restore to any person who has suffered any *ascertainable loss* by reason of the use or employment of such unlawful method, act or practice any moneys or property, real or personal, which may have been acquired by means of such method, act, or practice." (Emphasis added).

[11] *See* Bowley, *Law Enforcement's Role in Consumer Protection*, 14 Santa Clara Lawyer 555, 559 (1974) (inadequacy of existing injunctive remedy) [hereinafter cited as Bowley]; Comment, *Consumer Protection By Prosecutors*, 44 U. Cin. L. Rev. 81, 89 (1975) [hereinafter cited as *Consumer Protection by Prosecutors*]; Comment, *Consumer Protection: New Hope Following Failure of Civil and Criminal Remedies*, 66 J. Crim. L. & Criminology 271, 285 (1975); Staff Studies Prepared for the National Institute for Consumer Justice on 1) State and Federal Regulatory Agencies 2) Miscellaneous Redress Mechanisms 392 [hereinafter cited as Staff Studies].

[12] *See* Comment, *Civil Penalties — More or Less?*, 10 Gonzaga L. Rev. 669 (1975) [hereinafter cited as *Civil Penalties — More or Less*].

[13] Alaska Stat. § 45.50.551 (1974); Ariz. Rev. Stat. Ann. § 44-1531 (1967); Cal. Bus. & Prof. Code § 17536 (1965) (false advertising only); Conn. Gen.

Two important elements determining the effectiveness of a statute which imposes civil penalties are the burden of proof and the maximum permissible assessment of damages.

1. *Burden of Proof*

State statutes impose varying burdens of proof. Twelve of the states which impose civil penalties for initial violations require proof that the violation was willful, intentional or knowing.[18] Fifteen states do not require any showing of intent;[19] the

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Stat. Ann. § 42-110d (g) (1973); Ga. Code Ann. § 106-1216 (1975); Hawaii Rev. Stat. § 480.3.1 (1968); Ill. Ann. Stat. c. 121½ § 267 (1961); Kan. Stat. Ann. § 50-636 (1973); Ky. Rev. Stat. § 367.990 (1972); Md. Ann. Code Comm. Law § 13-410 (1975); Minn. Stat. Ann. § 325.8018 (1971) (restraint of trade); Miss. Code Ann. § 75-24-19 (1974); Mont. Rev. Code Ann. § 85-414 (1973); Neb. Rev. Stat. § 59-1614 (1974); Nev. Rev. Stat. § 598.640 (1973); N.H. Rev. Stat. Ann. § 358-A: 4 III(b) (1975); N.J. Stat. Ann. § 56:8-13 (1971); N.M. Stat. Ann. § 49-15-9 (1969); N.Y. Gen. Bus. Law § 350-C (1963) (false advertising only); Ore. Rev. Stat. § 646.642 (1971); S.C. Code Ann. § 66-71.10 (1971); S.D. Comp. Laws Ann. § 37-24-27 (1971); Tex. Bus. & Com. Code § 17.47 (1973); Vt. Stat. Ann. tit. 9 § 2458(b)(1) (1972); Rev. Code Wash. Ann. § 19.86.140 (1961); W. Va. Code Ann. § 46A-7-111 (1974); Wis. Stat. Ann. § 100.26(6) (1975) (unfair collection practices); V.I. Code tit. 12A § 104 (1973).

[14] *Consumer Protection by Prosecutors*, *supra* note 11 at 89; Bowley, *supra* note 11 at 559.

[15] *See* Black v. Sheraton Corp., 47 F.R.D. 263, 271 (D.D.C. 1969); Walker v. Sheldon, 10 N.Y.2d 401, 179 N.E.2d 497, 498 (1961).

[16] *See* Compton v. United States, 377 F.2d 408, 411 (8th Cir. 1967).

[17] *See* notes 53-57 *infra*, and accompanying text.

[18] Arizona, Connecticut, Georgia, Kentucky, Mississippi, Montana, Nevada, New Mexico, Oregon, South Carolina, South Dakota, West Virginia. *See* note 13, *supra*.

[19] Alaska, California, Hawaii, Illinois, Kansas, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, New York, Texas, Vermont, Washington, Wisconsin. *See* note 13, *supra*.

See also for California, Lorenz, *Consumer Fraud At The San Diego District Attorney's Office* 8 San Diego L. Rev. 47, 51 (1970) [hereinafter cited as Lorenz].

Virgin Islands incorporates both approaches by imposing a greater penalty where the law is knowingly violated.[20] The authors believe that proof of intent should not be required when the business community knows or in the exercise of reasonable care should know of its obligations. For example, knowledge of legal obligations imposed by unambiguous statutes, regulations, or case law should be presumed. However, it is unreasonably burdensome to impose upon a merchant the threat of penalty without any showing of intent to violate the law when the proscribed conduct is not clearly and unambiguously defined. Table I, below, categorizes the different burdens of proof required.

2. *Assessment of Penalties*

The maximum permissible assessment varies from a high of $50,000 for each violation in Illinois, to a low of $300 for each violation in Maryland. Two states, Maryland and New Jersey, impose one penalty for the first offense and allow a higher penalty for each subsequent offense.[21] Table I indicates the maximum permissible penalty in these states.

It should be noted that even the smallest maximum assessment can have a deterrent effect if judges impose multiple penalties for multiple offenses; however, a small penalty simply will not deter the constantly dishonest business operator.[22] Assessments imposed are frequently criticized as being much lower than the profits made by violating the law.[23] Large corporations can readily absorb penalties which are too small or pass them on to the consumer or stockholder in the form of higher prices and lower dividends.[24]

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[20] $350 civil penalty for each violation, $500 civil penalty for a knowing violation. V.I. CODE tit. 12A § 104.

[21] Maryland: $300 for each first violation and $500 for each subsequent violation. MD. ANN. CODE COMM. LAW § 13-410. New Jersey: $2,000 for each first violation and $5,000 for each subsequent violation. N.J. STAT. ANN. § 56: 8-13.

[22] LORENZ, *supra* note 19 at 50; Staff Studies, *supra* note 11 at 392.

[23] *See* Davids, *Penology and Corporate Crime*, 58 J. CRIM. L., CRIMINOLOGY & POLICE SCIENCE 524, 528 (1967); Comment, *Increasing Community Control Over Corporate Crime — A Problem in the Law of Sanctions*, 71 YALE L.J. 280, 285 (1961).

[24] *Consumer Protection By Prosecutors*, *supra* note 11 at 89.

In determining the size of the legally permissible assessment there are three issues to consider:

1. The importance to the public of deterring unfair and deceptive practices;
2. The amount of the damages that could be caused by violations of the consumer protection act; and
3. The size of the penalty necessary to deter future violations.[25]

The authors agree with those who believe that if the maximum permissible penalty is much below $5,000, its deterrent effect decreases substantially.[26]

TABLE I[27]

Burden of Proof and Assessment of Penalties

Maximum Permissible Penalty For Each Violation	Proof Required That Violation Was Willful Intentional, or Knowing	No Showing of Intent Required
$50,000		Illinois & Minnesota
$25,000	Oregon	
$10,000		Hawaii, New Hampshire, Texas, Vermont, Wisconsin
$ 5,000	Arizona, New Mexico, South Carolina, West Virginia	Alaska, New Jersey (second offense)
$ 2,500	Nevada	California
$ 2,000	Connecticut, Georgia, Kentucky, South Dakota	Kansas, Nebraska, New Jersey (first offense), Washington
$ 500	Mississippi, Montana, Virgin Islands	Maryland (2nd offense) New York
$ 350		Virgin Islands
$ 300		Maryland (1st offense)

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[25] *See Civil Penalties — More or Less, supra* note 12 at 670.

[26] *See, e.g.*, Lovett, *State Deceptive Trade Practices Legislation*, 46 TULANE L. REV. 724, 739 n.51 (1972).

[27] *See* note 13 *supra*; *see also*, for California, LORENZ, *supra* note 19.

II. CRIMINAL PROSECUTION

An effective consumer protection program must involve not only civil actions but criminal prosecutions as well. Criminal prosecution is the public enforcement weapon which affords the greatest deterrent effect.[28] Members of business and professional communities generally abhor being branded criminals regardless of which law they may have violated.[29] Conviction strips the offender of his cloak of respectability and may bar him from the pursuit of his chosen career.[30] The effectiveness of criminal sanctions is vividly displayed by the pressure the business community exerts against use of these sanctions.[31] Furthermore, criminal conviction results in a sentence which cannot be avoided by a judgment-proof operator. These sentences also provide some satisfaction to defrauded consumers who demand equitable retribution where restitution is unavailable.

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[28] *See* Ball and Friedman, *The Use of Criminal Sanctions In the Enforcement of Economic Legislation: A Sociological View*, 17 STAN. L. REV. 197, 216 (1965) [hereinafter cited as BALL]; Geis and Edelhertz, *Criminal Law and Consumer Fraud: A Sociological View*, 11 AM. CRIM. L. REV. 989, 1005 (1975); Givens, *Roadblocks to Remedy in Consumers Fraud*, 24 CASE W. L. REV. 144 (1972). For example, since 1968 the Fraud Division of the U.S. District Attorney's Office for the District of Columbia has had to indict only one home improvement scheme. This was attributed to a number of successful prosecutions in the late sixties believed to deter potential offenders. Rothchild and Throne, *Criminal Consumer Fraud: A Victim Oriented Analysis*, 74 MICH. L. REV. 661, 693 (1976) [hereinafter cited as ROTHCHILD]. *See generally* National Institute of Law Enforcement and Criminal Justice, *Exemplary Projects: Prosecution of Economic Crime.*

[29] BALL, *supra* note 28 at 217; Staff Studies, *supra* note 11 at 391.

[30] Ogren, *The Ineffectiveness of the Criminal Sanction in Fraud and Corruption Cases: Losing the Battle Against White Collar Crime*, 11 AM. CRIM. L. REV. 959, 985 (1973) [hereinafter cited as OGREN].

[31] BALL, *supra* note 28 at 217; *e.g.* Testimony of Albert B. Perlin, Jr., on behalf of the National Retail Merchants Association before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce regarding S. 670 (August 9, 1976). The issue is whether criminal sanctions ought to be imposed on those who violate the legal but not the moral code. BALL, *supra*, note 28 at 199. However, consumer fraud well merits severe punishment. The victim has lost more than property, he has lost the security in transactions with other members of society which is gained only through fair dealings. *Consumer Protection by Prosecutors, supra* note 11 at 91. This loss of confidence in the free market system makes the legitimate businessman a victim as well. Testimony of Louis J. Lefkowitz, Attorney General of New York, before the Executive and Legislative Reorganizing Subcommittee on Government Operations (April 29, 1966), (reported in *Placement of State Consumer Protection Programs*, Consumer Protection Special Report, February 1976, National Association of Attorneys General at 1 n.1; *See also* RAMSEY CLARK, CRIME IN AMERICA 38 (1970).

A. *Traditional Larceny Statutes*

In the absence of specific statutes which provide for criminal prosecution of economic crimes, larceny by false pretenses may be construed to prohibit unfair and deceptive trade practices. The value of such statutes to prosecutors and their effectiveness as a deterrent to economic crime depends on the extent of the burden of proof placed on the prosecution and the maximum permissible sentence and/or fine. As Table II indicates, the maximum permissible sentence and/or fine varies from a low in Hawaii of one year and/or a $1,000 fine to a high in Arkansas of twenty years and/or a fine of $15,000 or twice the pecuniary gain from the illegal act.

TABLE II — *Larceny Statutes*[82]

Maximum Sentence	Maximum Fine In Addition	Maximum Fine In Alternative	No Fine
20 years	Arkansas ($15,000)[*] Connecticut ($10,000) Texas ($10,000)		Virginia[1]
15 years	Utah ($10,000) Wisconsin ($10,000) New Hampshire ($2,000) Maryland ($1,000)		
14 years			Idaho Montana

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[82] ALA. CODE c. 14 § 331 (1962); ALASKA STAT. § 11.20.140 (1949); ARIZ. REV. STAT. ANN. § 13-671 (1974); ARK. STAT. ANN. §§ 41-901, 41-2203 (1975); CAL. PENAL CODE § 489 (1953); COLO. REV. STAT. ANN. §§ 18-1-105, 18-4-401 (1963); CONN. GEN. STAT. ANN. §§ 53a-35, 53a-41, 53a-122 (1971); DEL. CODE ANN. tit. 11 §§ 841, 4205 (1953); FLA. STAT. ANN. §§ 775.082, 775.083, 812.021 (1975); GA. STAT. ANN. § 26-1812 (1972); HAWAII REV. STAT. § 750-19 (1955); IDAHO CODE ANN. § 18-4606 (1864); ILL. ANN. STAT. ch. 38 §§ 16-1, 1005-8-1, 1005-9-1 (1973); IND. P. L. 148, art. 43 ch. 4 § 2, 1976 IND. ACTS art. 50, ch. 2 § 7; IOWA CODE ANN. § 709.2 KAN. STAT. ANN. §§ 21-3701, 21-4501, 21-4503 (1972); KY. REV. STAT. §§ 514.040, 532.060, 534.030 (1974); LA. STAT. ANN. § 14-67 (1972); ME. REV. STAT. ANN. tit 17-A §§ 362, 1252, 1301 (1976); MD. ANN. CODE art. 27 § 340 (1974); MASS. GEN. LAWS ch. 266 § 30 (1967); MICH. COMP. LAWS

Maximum Sentence	Maximum Fine In Addition	Maximum Fine In Alternative	No Fine
10 years	Colorado ($30,000) Guam ($10,000) Illinois ($10,000) Maine ($10,000)[ii] Minnesota ($10,000) North Dakota ($10,000) South Dakota ($10,000) Washington ($10,000) Kansas ($5,000) Nevada ($5,000) New Mexico ($5,000) Louisiana ($3,000)[iii] Missouri ($1,000) Vermont ($500) North Carolina		Alabama Alaska Arizona California Georgia Puerto Rico South Carolina Tennessee West Virginia Wyoming District of Columbia Virgin Islands
7 years	Pennsylvania ($15,000) New Jersey ($2,000) New York[ii] Delaware[iv]		Nebraska
5 years	Kentucky ($10,000)[v] Florida ($5,000) Ohio ($2,500) Oregon ($2,500)[v] Iowa ($1,000) Mississippi ($1,000) Rhode Island ($1,000)	Michigan ($2,500)	Missouri Massachusetts[i]
4 years	Indiana ($10,000)		
2 years	Massachusetts ($600)[i]		
1 year	Hawaii ($1,000) Oklahoma ($1,000) Virginia ($1,000)[i]		

Ann. § 750.356 Minn. Stat. Ann. § 609.52 (1976); Miss. Code Ann. § 97-17-41 (1966); Mo. Ann. Stat. §§ 560.156, 560.161 (1975); Mont. Rev. Code Ann. § 94-2706 (1921); Neb. Rev. Stat. § 28-506 (1974); Nev. Rev. Stat. § 205.220 (1969); N.H. Rev. Stat. Ann. §§ 637:4, 637:11, 651:2 (1973); N.J. Stat. Ann. §§ 2A:85-6, 2A:119-2 (1957); N.M. Stat. Ann. §§ 40A-16-1, 40A-29-3 (1969); N. Y. Penal Law §§ 70.00, 80.00, 155.35 (1965); N.C. Gen. Stat. § 14-100 (1975); N.D. Cent. Code §§ 12.1-23-05, 12.1-32-01 (1975); Ohio Rev. Code §§ 2913.02, 2929.11 (1974); Okla. Stat. Ann. ch. 21 § 1541.1 Ore. Rev. Stat. tit. 16 §§ 161.605, 161.625, 164.055 (1971); Pa. Stat. Ann. ch. 18 § 1101, 1103, 3903 (1973); Laws Of P.R. tit. 33 § 4272 (1974); R.I. Gen. Laws Ann. § 11-41-5 (1956); S.C. Code Ann. §§ 16-11, 17-552 (1972); S.D. Comp. Laws Ann. §§ 22-30A-3, 22-30A-17, 22-6-1 (1975); Tenn. Code Ann. § 39-4204 (1932); Tex. Penal Code §§ 12.33,

The greatest problem faced by the prosecution in establishing a *prima facie* case of larceny by false pretenses is the burden of proving intent to defraud. In Massachusetts, for example, the prosecution is hampered by inappropriate and unrealistic burdens imposed by a statute which was not originally enacted as a tool to protect consumers.[83] For instance, if a consumer purchases a "lifetime" contract from a health spa which closes its doors shortly after selling the contract,[84] or a consumer places a deposit on a trip which is cancelled and never receives his money back, the prosecutor must prove that there was an intent to defraud at the time the money was taken.[85] Proof that the wrongful act occurred with evidence that the operator failed to disclose information which would have affected the consumer's judgment, or evidence of the operator's failure to correct a previous-

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31.03 (1975); Utah Code Ann. §§ 76-3-203, 76-3-301, 76-6-412 (1975); Vt. Stat. Ann. tit. 13 § 2501 (1972); Va. Code Ann. § 18.2-95 (1975); Rev. Code Wash. Ann. §§ 9A.56.030, 9A.20.020 (1961); W. Va. Code Ann. § 61-3-13 (1957); Wis. Stat. Ann. § 943.20 (1955); Wyo. Stat. Ann. § 6-132 (1973); D.C. Code § 22-2201 (1953); Guam Penal Code § 489 V.I. Code tit. 14 § 1083 (1941). Note that these statutes apply to larceny or theft by a person. Some states impose a higher fine where the crime is committed by a corporation. *See e.g.* Ore. Rev. Stat. tit. 16 § 161.655 (1971).

i. one of two possible atlernatives
ii. and/or double the gain from the theft
iii. with or without hard labor at court's discretion
iv. fine in court's discretion
v. or double the gain from the theft, whichever is greater

[83] Mass. Gen. Laws ch. 266 § 33 (1932). To constitute the crime of larceny by false pretenses in Massachusetts, it must appear that there was a false statement of fact or present intention known or believed by the defendant to be false, made with the intent that the person to whom it was made should rely upon its truth, and that such person did rely upon it as true and parted with personal property as a result of such reliance. Commonwealth v. Green, 326 Mass. 344, 348, 94 N.E.2d 260, 263 (1950); Commonwealth v. Louis Construction Co. Inc., 343 Mass. 600, 604 (1962). Note, however, Mass. Gen. Laws ch. 175 § 176 (1932) establishes an evidentiary presumption which reduces the prosecutor's burden of proof in cases where insurance agents fail to pay premiums over to the Insurance Companies. Commonwealth v. Baker, 1975 Mass. Adv. Sh. 1875, 1909-10, 330 N.E.2d 794, 808.

[84] *See* Commonwealth v. International Health Spas, Massachusetts Supreme Judicial Court C.A. 7591 (filed March 28, 1975).

[85] *See* Commonwealth v. Quality Travel Corp., Massachusetts Superior Court C.A. 117612 (filed Norfolk Superior Ct. February 24, 1976).

ly created or reinforced false impression, should be, but is not, sufficient to establish a *prima facie* case.[36]

Another problem with traditional criminal laws concerns their applicability to corporate officers who attempt to insulate themselves from personal liability for their fraudulent practices within a protective corporate framework. Under existing Massachusetts law, for example, corporate officers and directors may be held personally liable for criminal acts only as narrowly provided by statute[37] or as provided by restrictive common law.[38] The criminal liability of corporate officers and directors should be in accord with the recognized responsibility of corporate officers to be aware of their corporation's activities where they stand in a responsible relation to a public danger.[39] Federal courts recently have held that criminal liability may attach to a corporate officer or director who has "deliberately closed his eyes to the obvious."[40]

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[36] *See* American Law Institute, Model Penal Code § 223.3 (1962) [hereinafter Model Penal Code].

[37] *See* Mass. Gen. Laws ch. 266 §§ 65-67 (1972).

[38] Massachusetts common law attaches criminal liability to an officer or director when he is actually present and an efficient actor in committing the offense, United States v. Winslow, 175 F. Supp. 578, 581 (D. Mass. 1972); or where the officer or director directed and assented to the unlawful act, Commonwealth v. Abbot Engineering, 351 Mass. 568, 580, 222 N.E.2d 862 (1967); or where the officer or director "participated in the act or countenanced it or otherwise approved it," Commonwealth v. Riley, 196 Mass. 60, 62, 81 N.E. 881, 882 (1907).

[39] United States v. Park, 421 U.S. 658, 670-73 (1975) wherein the Supreme Court upheld the criminal conviction of an executive of a national retail food chain for violation by his company of a provision of the Federal Food Drug and Cosmetic Act despite his defense that he was not personally responsible for the action constituting the basis of the charge. The court noted that the purpose of the act was to protect people who were beyond self-protection and in the interest of the larger good the burden of awareness was placed on the person standing in a responsible relation to a public danger.

[40] United States v. Natelli et al., 527 F.2d 311 (2d Cir. 1975) cert. den. 96 S.Ct. 1663 (1976). Federal cases have found the requisite criminal intent where the defendant: (1) made statements with reckless indifference or disregard as to whether they are true or false; (2) closed his eyes to what was plainly to be seen; (3) acted with a conscious purpose to avoid learning the truth; (4) failed to exercise due diligence to ascertain the truth; (5) acted with such gross carelessness and indifference to the truth of the representation contained in the statement as to warrant the conclusion that he acted fraudulently. Curnow, *Economic Crime, A High Standard of Care* 5 Fed. Bar J. 21, 23 (1976).

B. *Model Penal Code: Deceptive Business Practice Act*

The need to revise traditional larceny statutes has been recognized by many states. The American Law Institute has reported that as of April, 1976, twenty-nine states have revised their criminal code.[41] Of those, at least five have revised their larceny statutes along the lines of the Model Penal Code.[42] Under the Code, proof of facts other than intent to defraud carries the prosecution's burden of proof in numerous instances.[43]

The Model Penal Code includes a Criminal Deceptive Business Practice Act. Under the act, proof that the specifically proscribed conduct occurred is sufficient to establish a *prima facie* case without any showing of intent to defraud. At least four states have enacted statutes modeled after this Act.[44] However, constitutional standards limit the extent to which inferences may be established by statute.[45]

At least sixteen of the twenty-nine states reported to have revised their criminal codes have adopted provisions similar to the Model Penal Code defining the personal liability of corporate officers in accordance with the recognized public responsibility of the business community.[46] Under the Model Penal Code a corporate officer or director is liable for any conduct he performs or causes to be performed in the name of the organization or in its behalf to the same extent as if it were performed in his own name or behalf. Criminal liability is also imposed where the agent having primary responsibility for the discharge of a duty recklessly omits to perform the required act.[47]

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[41] *See* American Law Institute, ANNUAL REPORT OF THE 53RD ANNUAL MEETING 19 (1976).

[42] COLO. REV. STAT. ANN. § 18-4-401; N.H. REV. STAT. ANN. § 637:44; ILL. ANN. STAT. ch. 38 § 16-1; N.D. CENT. CODE § 12.1-23-02; PA. STAT. ANN. ch. 18 § 3922.

[43] MODEL PENAL CODE, *supra* note 36 at § 223.3.

[44] KAN. STAT. ANN. § 21-4403 (1970); KY. REV. STAT. § 517.020 (1974); N.Y. PENAL LAW ch. 39 §§ 190.60 and 190.65 (1976); UTAH CODE ANN. § 76-6-507 (1973). *See also* WIS STAT. ANN. § 100.26. *See also* PROPOSED CRIMINAL CODE OF MASSACHUSETTS ch. 266 § 32 (1962) [hereinafter cited as PCCM].

[45] A statutory inference is constitutional if the presumed fact is more likely than not to flow from the proved fact, and there is a rational connection between the proved fact and the presumed fact. Barnes v. United States, 412 U.S. 837, 842 (1975). Moreover, although intent is typically considered a fact peculiarly within the knowledge of the defendant, this does not justify shifting the burden to him. Unique hardship on the prosecution may, however, justify requiring the defendant to carry the burden of proving a fact critical to criminal culpability; *e.g.* presumption of sanity. Mullaney v. Williams, 95 S.Ct. 1881, 1891 (1975). In the interest of the public good the burden may be shifted to the defendant where he stands in a responsible relation to a public danger. United States v. Park, 421 U.S. 658, 670-73 (1975); *see* note 39, *supra*. Note however that in a criminal case the trier of facts is permitted, but not compelled, to draw from the basic fact the statutory inference. Commonwealth v. Pauley, 331 N.E.2d 901 (Mass. 1975).

C. *Criminal Sanctions for Violation of the Consumer Protection Act*

Although a consumer protection act is a civil statute, it may also provide criminal sanctions. Presently, six states impose criminal sanctions for violations of their consumer protection act. Five of these states provide for a maximum sentence of one year in prison and/or fines ranging from a high of $10,000 in Alaska, to a low of $250 in Arkansas.[48] Three of the states, Alaska, Maryland and New Hampshire, do not require any proof that the violation was knowing, willful or intentional.[49]

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[46] Ark. Stat. Ann. § 41-403 (1974); Colo. Rev. Stat. Ann. § 18-1-607 (1973); Conn. Gen. Stat. Ann. § 53a-11 (1958); Del. Code Ann. tit. 11, § 282 (1974); Ga. Code Ann. § 26-801 (1972); Ill. Ann. Stat. ch. 38 § 5-5 (1972); Kan. Stat. Ann. ch. 21 § 3207 (1974); Ky. Rev. Stat. § 502.060 (1975); Me. Rev. Stat. Ann. 17-A, § 61 (1964); N.Y. Penal Law ch. 39 § 20.25 (1975); N.D. Cent. Code § 12.1-03-03 (1976); Ohio Rev. Code § 2901.24 (1975); Ore. Rev. Stat. tit. 16 § 161.175 (1975); Pa. Stat. Ann. c. 18 § 307(e) (1973); Tex. Penal Code § 7.23 (1974); Utah Code Ann. § 76-2-205 (1953).

[47] Model Penal Code, *supra* note 36 at § 2.07(6). *See also* PCCM, *supra* note 44 at ch. 263, § 23.

[48] Alaska Stat. § 45.50.551, $10,000 fine and/or one year in prison; Ark. Stat. Ann. § 70-907, $250 fine and/or one year in prison; Md. Ann. Code Comm. Law tit. 13 § 411, $1,000 fine and/or one year in prison; Mont. Rev. Code Ann. § 85-414, $2,000 fine and/or one year in prison; Nev. Rev. Stat. §§ 598.640 and 193.150, $500 fine and/or 6 months in prison; N.H. Rev. Stat. Ann. §§ 358-A:6 and 651:2 (1975), $1,000 fine and/or one year in prison for natural person, $50,000 fine for others. *See also* Wis. Stat. Ann. § 100.26.

[49] Note, however, that Alaska has not brought any criminal prosecutions under this act partly because of serious constitutional questions which would prevent successful prosecution. Letter from Stanley T. Fischer, Chief of the Consumer Protection Section of Alaska's Office of the Attorney General dated November 26, 1976. Partly for the same reason, New Hampshire is reluctant to use its statute and has brought only one prosecution, unsuccessfully, under the Act. Telephone conversation with New Hampshire Assistant Attorney General John Funk on

Although the direct imposition of criminal sanctions for violations of the consumer protection act obviates the prosecutor's problems of tailoring specific conduct to existing larceny statutes or other economic crime statutes, it is not necessarily desirable or effective. Criminal sanctions may provide the operator with Fifth Amendment grounds of self-incrimination to avoid divulging otherwise discoverable matter in civil actions brought by consumers as well as the state.[50] In addition, the obligation of the courts to strictly construe criminal statutes could force strict construction of the statute in civil actions as well.[51] Furthermore, there may be serious constitutional questions of due process unless the statute is precisely drawn.[52] These consid-

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December 6, 1976. Maryland has brought criminal prosecutions under her act only rarely and John N. Ruth, Jr., Chief of the Maryland Attorney General's Consumer Protection Division, has indicated the criminal provision is a troublesome section. Letter from John N. Ruth Jr. dated December 2, 1976.

[50] Massachusetts prosecutors cannot grant immunity to the operator to compel testimony because MASS. GEN. LAWS c. 233 §§ 20C-20F do not apply to civil trials. *But see* People v. Superior Court of Los Angeles, 525 Pa.2d 716 (Cal. 1974) wherein the court issued a protective order under California's code of civil procedure to protect parties or witnesses from "annoyance, embarrassment or oppression" and further stated that no specific legislative authorization for judicial grants of immunity is required. *See* MASS. R. CIV. P. 26(c). In addition, the Fifth Amendment privilege provides limited protection: (1) the Fifth Amendment is designed to protect "evidence of a testimonial or communicative nature," not previously recorded tangible business records. See, *Schmerber v. California*, 384 U.S. 757, 761 (1966); (2) the right to be free from self-incrimination is a personal right applying only to natural persons and cannot be exercised by a business entity. *Hale v. Henkel*, 201 U.S. 43, 74-75 (1906); *U.S. v. Kordel*, 397 U.S. 1, 7 (1970). Although an individual may not be compelled by subpoena to produce documents which would incriminate him, *Fisher v. U.S.*, 19 Crim. Law Reporter 3018 (1976), documents seized by search warrant may be introduced as evidence, *Andersen v. Maryland*, 19 Crim. Law Reporter 3183 (1976). *See infra* note 66 and accompanying text.

[51] *See* Commonwealth by Creamer v. Monumental Properties, Inc., 314 A.2d 333, 337-38 (Pa. 1973); *but see* Turner v. Koscott Interplanetary, Inc., 191 N.W.2d 624, 629 (Iowa 1971) wherein the court held that the act is to be interpreted liberally where a remedy is sought, and strictly when the action brought is criminal.

[52] *See* note 49 *supra*, for indications to this effect from prosecutors in states which include criminal sanctions in their consumer protection act. Due process challenges that the statute is void for vagueness turn on the wording of the phrases challenged as unduly imprecise. As guides to make terms which are challenged as unconstitutionally vague more precise, courts have made reference to standard dictionaries, People v. Witzerman, 105 Cal. Rptr. 284, 291 (Cal. App. 1972), common sense and legislative intent, Kugler v. Market Development Corp., 306 A.2d 489, 492 (N.J. 1973); common law and federal trade law, State v. Readers Digest Association, Inc., 501 P.2d 290, 301 (Wash. 1972).

erations argue against the desirability of criminal sanctions for violations of a consumer protection act.

D. *Use of the Criminal Statutes*

Although revisions of criminal statutes to distribute the burden of proof realistically in accordance with the interests of the public and the recognized responsibilities of the business community enhance the attractiveness of criminal prosecution as a tool to prevent unfair and deceptive trade practices, criminal prosecution is appropriate in only a limited number of situations. An overriding policy concern is whether the violation of law is severe enough to merit a criminal sanction. In this regard, the prosecutor must consider the need for strong deterrent measures to discourage others from the commission of like offenses as well as society's demand for discipline or punishment of the wrongdoer.

Even if criminal prosecution is deemed appropriate, there are problems generally associated with the prosecution of economic crimes which must be resolved. Because a criminal conviction requires a higher standard of proof than a civil action, more sophisticated investigations may be required to establish a *prima facie* case in a criminal trial than in a civil trial. For the same reason, criminal trials tend to be longer and more complicated than civil trials.[53] In addition, because an injunction is unavailable in a criminal prosecution, the criminal defendant may continue operating with impunity right up to the time of trial.[54]

Criminal convictions in economic crime cases generally result in light sentences;[55] and, even if a substantial penal sentence is imposed, criminal consumer fraud offenders rarely remain confined for more than the minimum term.[56] Finally, a criminal prosecution does not necessarily provide restitution for the victims. However, restitution is commonly suggested by the defendant in negotiations with the prosecutor, in open court as a factor justifying a more lenient sentence, or may be considered by the judge as a condition of probation.[57]

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[53] *See*, Saxby, *The Role of the Government in Consumer Protection: The Consumer Frauds and Crimes Section of the Office of the Ohio Attorney General*, 29 OHIO STATE L. J. 897, 904 (1968); Edelhertz, *The Nature Impact and Prosecution of White Collar Crime*, National Institute of Law Enforcement and Criminal Justice, at 39-40 [hereinafter cited as EDELHERTZ]; OGREN, *supra* note 30 at 960; ROTHCHILD, *supra* note 28 at 684-87.

[54] Because the court has no statutory authority to issue an injunction in a criminal prosecution it may be necessary to institute a civil action seeking injunctive relief. *See infra* note 64 and accompanying text.

[55] ROTHCHILD, *supra* note 28 at 686; EDELHERTZ, *supra* note 53 at 58-59. Bernard Bergman, a central figure in the New York nursing home scandal, was sentenced

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by United States District Court Judge Marvin Frankel to serve four months in Federal Correction Center. Mr. Bergman pleaded guilty to two counts of a federal indictment alleging Medicaid and tax frauds of 1.2 million dollars and to a state indictment charging the bribery of Albert H. Blumenthal, the majority leader of the New York assembly.

During the sentencing proceedings, Judge Frankel read from a long memorandum in which he discussed the theory of sentencing. He described the four-month sentence as stern. Judge Frankel acknowledged that the defendant's actions had been blatant and unmitigated. He balanced these facts by observing that Mr. Bergman was an elderly man whose life was marked by illustrious public works. Judge Frankel stated: "The case calls for a sentence that is more than nominal. Given the other circumstances — including that this is a first offense by a man no longer young and not perfectly well, where danger of recidivism is not a concern — it verges on cruelty to think of confinement for a term of years."

Charles J. Hynes, Special Prosecutor for Nursing Home Violations, stated that he was "extraordinarily disappointed" by the sentence. He expressed a fear that the sentence would encourage public cynicism about special justice for the elderly and would also damage the continuing investigation into nursing home abuses. The special prosecutor said that Mr. Bergman had made a "palpably absurd" offer to repay $367,000 defrauded from Medicaid; the state auditors had uncovered thefts totalling 2.5 million dollars. Mr. Hynes also stated the defendant had been less than forthcoming in cooperating with the special prosecutor's office in the ongoing investigation into nursing home abuses in violation of the plea bargain agreement reached by attorneys for Mr. Bergman and federal and state prosecutors. Mr. Hynes also stated that he would consider reopening the prosecution of Mr. Bergman in state court. Reported in III Economic Crime Digest 164-65 (National District Attorneys' Assoc.).

[56] Rothchild, *supra* note 28 at 686-87.

[57] *See* 18 U.S.C. § 3651 (1970) Mass. Gen. Laws ch. 276 § 92 (1972); Me. Rev. Stat. Ann. tit. 17-A § 1204 (1976); N.M. Stat. Ann. § 40A-29-18 (1953); N.D. Cent. Code § 12.1-32-07 Model Penal Code § .301.1 (1962); PCCM, *supra* note 54, at ch. 264, § 21 (these statutes make restitution a legislative guideline for probation). *See also* MD. Ann. Code art. 27, § 340 (1976); Neb. Rev. Stat. § 28-506 (1974); N.D. Cent. Code § 12.1-32-08 (1976); S.C. Code Ann. § 17-559 (1972) (these statutes compel restitution as part of the sentence). In the absence of appropriate criminal statutes or procedures the prosecutor must consider instituting a civil action to obtain restitution for defrauded consumers. *See also* Utah Code Ann. § 76-6-412 (1953), which allows the injured party to bring action for treble damages, costs and attorneys fees.

III. TACTICAL CONSIDERATIONS — THE INTEGRATION OF CIVIL AND CRIMINAL REMEDIES

The integration of civil and criminal remedies in one consumer protection program is essential to achieve the objectives of deterring fraudulent practices and compensating victims in a timely and efficient manner.[58]

A. *Considerations at the Investigative Stage*

In a co-ordinated consumer protection program, the enforcing agency should make an initial determination at the investigative stage of whether to proceed civilly, criminally, or both. Such a determination should be based on criteria which the prosecutor, in his experience, has found significant, such as: (1) available resources; (2) target priorities to alleviate particular problems; (3) the need for immediate temporary relief; and, (4) the likelihood of success in a criminal prosecution.

State consumer protection acts typically contain authorization for the administering or enforcement official to conduct investigations through use of subpoenas.[59] However, some states prohibit the use of information obtained thereby in a subsequent criminal proceeding.[60] This limited form of subpoena is commonly referred to in Massachusetts as a Civil Investigative Demand (CID).

The CID gives the enforcing agency, prior to the filing of a complaint and without any showing of probable cause, the right to inspect and copy business records which may be relevant to an investigation. The CID may also compel the attendance of a person at a deposition under oath. It may be issued whenever the enforcing agency believes a violation of the Consumer Protection Act has occurred, or to assure the enforcing agency that the law is not being violated.[61] In a criminal investigation, on the other hand, a warrant to search and seize is available only after there has been a showing to a neutral, detached magistrate that there is probable cause to believe that contraband, fruits, instrumentalities or evidence of a crime are present in the place to be searched.[62] However, these and other considerations surrounding the choice of pre-litigation tools are obviated in states where the Attorney General has broad subpoena powers.[63] Evidence obtained thereby may be admitted in either a civil or criminal proceeding.

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[58] *See* EDELHERTZ, *supra* note 53 at 38-44.

[59] FTC FACT SHEET, *supra* note 2.

[60] *E.g.* MD. ANN. CODE COMM. LAW § 13-405 (Michie, 1975); MASS. GEN. LAWS ch. 93A, § 6 (1972); PA. STAT. ANN. ch. 73 § 201-6 (1971); S.C. CODE ANN. § 66-71.6 (1972); REV. CODE WASH. ANN. § 19.86.110 (1961).

[61] United States v. Morton Salt, 338 U.S. 632, 642-643 (1950); MASS. GEN. LAWS ch. 93A, § 6.

B. *Consideration at the Litigation Stage*

After the investigative stage, a re-evaluation should take place to determine whether to file a civil suit, seek a criminal indictment, or both. In addition to considering the criteria relevant at the investigative stage, this second determination should be based on how best to deter the activity from recurring in the future and how best to rectify the present situation. In a civil action, for instance, a temporary restraining order and preliminary injunction are available to immediately halt unlawful practices.[64] In certain situations, therefore, it might be advisable to initiate a civil action for the purpose of obtaining a restraining order and injunction, and subsequently seek a criminal indictment after the unlawful practices have been stopped.

There are numerous general factors which tend to support the pursuit of civil rather than criminal remedies. In a civil action:

1. The defendant may not have the right to a jury trial.[65]
2. There is a less onerous burden of proof on the plaintiff.

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[62] United States v. Harris, 403 U.S. 573 (1971); Spinelli v. United States, 393 U.S. 410 (1969); Warden v. Hayden, 387 U.S. 294 (1967).

[63] *E.g.* ALASKA STAT. § 45.50.495 (1976); ARK. STAT. ANN. § 70-909 (1964); COLO. REV. STAT. § 6-1-108 (1973); W. VA. CODE ANN. § 46A-7-104 (1976).

[64] *E.g.* MASS. GEN. LAWS ch. 93A, § 4.

[65] The Seventh Amendment does not control the actions of the states in abridging trial by jury but applies only to the courts and Congress of the United States. Minn. & St. Louis R.R. v. Bombolis, 241 U.S. 211, 217 (1916), Vallavanti v. Armour & Co., 264 Mass. 337, 342, 162 N.E. 689 (1928). Because injunctive relief and

3. The defendant's Fifth Amendment rights against self-incrimination are more limited.[66]

4. There are tools of discovery that are not available to the state in a criminal action.

5. Restitution may be obtained by order of the court.[67]

6. The resolution of proceedings may be more rapid.

7. A suit may be maintained even against an out-of-state defendant,[68] thus avoiding cumbersome extradition proceedings under a criminal indictment.[69]

8. The state may appeal an unfavorable decision, but is barred from doing so in a criminal prosecution on grounds of double jeopardy.[70]

9. The defendant has no constitutional right to be confronted by the witnesses against him.[71]

These considerations must be weighed against the known advantages of a criminal prosecution:

1. Successful criminal prosecution of several offenders acts as a significant deterrent to other prospective offenders.[72]

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restitution are equitable remedies, parties are not entitled to a jury; parties are not ordinarily entitled as of right to a jury trial in equity cases. McAdams v. Milk, 332 Mass. 364, 367, 125 N.E.2d 122 (1955); *See also* Kugler v. Market Development Corp., 306 A.2d 489 (N.J. 1973) in which the court held the defendant was not entitled to jury trial in a civil action by the state to enforce the state Consumer Protection Act. People v. Witzerman, 105 Cal. Rptr. 284, 289 (Cal. App. 1972).

[66] *See* note 65, *supra*. Where there is a possibility that evidence obtained from an individual is to be used in a subsequent criminal proceeding against that individual, the invocation of Fifth Amendment privilege may be proper. *U.S. v. Churchill*, 483 F.2d 268, 272 (1973); *U.S. v. Kordell*, 397 U.S. 1, 7-8 (1969); however, the Fifth Amendment does not forbid adverse inferences to be drawn against parties to a civil action who choose to exercise this privilege. *Baxter v. Palmigiano*, 96 S.Ct. 1551, 1558 (1976). See also *supra* note 50.

[67] *E.g.* MASS. GEN. LAWS ch. 93A § 4. *But see* note 57 *supra* and accompanying text.

[68] *E.g.* Massachusetts Long Arm Statute, MASS. GEN. LAWS ch. 223A, § 1 *et seq.* (1972).

[69] *E.g.* MASS. GEN. LAWS ch. 276 §§ 11 *et seq.* (1972).

[70] Helvering v. Mitchell, 303 U.S. 391, 402-04 (1938).

[71] *Id.*

[72] *See* notes 28-31 *supra* and accompanying text.

2. The habitual consumer-fraud offender may be isolated from society for a period of time.[73]

3. Criminal acquittal does not bar a subsequent civil action on the ground of double jeopardy.[74]

In order to determine the most efficient and effective plan of action, each case must be evaluated on its own merits in terms of the competing considerations discussed above. Therefore, consumer problems should be referred to one centralized agency capable of implementing an integrated approach. An agency which is not versed in both civil and criminal consumer protection statutes will be handicapped in its efforts to discern and pursue the most appropriate available remedies.[75]

IV. CONCLUSION

Effective consumer protection programs are dependent upon the coordination of both civil and criminal remedies which must provide for measurably strong sanctions if they are to be effective.[76] The potential offender must be given notice that if he pursues a deceptive course of conduct, he will be severely penalized.[77]

The private right of action alone is not adequate because many consumers do not know when they have been cheated,[78] are ignorant of their rights,[79] or are discouraged by the high cost of litigation as compared to their individual loss.[80] In addition, the response of federal enforcement agencies to the immediate needs of defrauded consumers is too limited.[81] For these reasons, an aggressive state authority, capable of seeking sanctions of recognizable severity is necessary to deter unfair and deceptive trade practices.

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[73] ROTHCHILD, *supra* note 28, at 690.

[74] BOWLEY, *supra* note 11, at 565.

[75] *E.g.* the Maryland Attorney General has no criminal jurisdiction and must rely on local state's attorneys. Although several matters have been referred to local state's attorneys, criminal actions are rarely brought. Letter from John N. Ruth, *supra* N. 49. The Alaska Attorney General's Consumer Protection Section has no personal experience in criminal law and there is an apparent unwillingness on the part of the state's criminal prosecution staff to handle consumer fraud. Letter from Stanley T. Fischer *supra* N. 49.

[76] Rice, *Remedies, Enforcement Procedures and the Duality of Consumer Transaction Problems*, 48 B.U. L. REV. 559, 609 (1968) [hereinafter cited as RICE].

[77] *See* ROTHCHILD, *supra* note 28 at 690-91, 693.

[78] *See Consumer Protection by Prosecutors, supra* note 11 at 84.

[79] State Programs for Consumer Protection 44 (National Association of Attorneys General, 1973).

An effective state legislative program should include, at a minimum, a consumer protection act with civil penalties for initial violations as well as criminal statutes appropriate for the prosecution of economic crimes. This may mean revising existing larceny statutes as well as enacting legislation directed specifically at problems of consumer fraud.

Legislation which protects consumers protects honest merchants as well. Whenever a consumer is defrauded, an honest merchant is injured, because he has lost a sale to a customer who has been induced to buy from the dishonest merchant offering "a better deal." Furthermore, when the consumer learns he has been unfairly treated he may be apprehensive when dealing with anyone in that business because he is not willing to assume the risk of loss attendant upon another unfair transaction. Aggressive enforcement of effective consumer legislation fosters an atmosphere in which the consumer develops greater confidence in the free market system since businesses are responsive to legitimate grievances. This increase in confidence influences consumer demand for goods and services to the benefit of the entire community, merchants as well as consumers.[82]

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[80] Id.; RICE, *supra* note 76 at 567-570.

[81] FTC proceedings generally involve extensive delays. Cases can take about a year to reach the Commission in the first place for the issuance of a complaint. Cohen, *Comparative False Advertising Legislation: A Beginning* 4 ADELAIDE L. REV. 69, 90 (1971). Efforts to provide restitution through federal proceedings would be cumbersome considering the possible need to give the defendant a hearing in every jurisdiction where the alleged violation occurred and as to every consumer claimant; and federal budgets will never be sufficiently large nor federal personnel so numerous to protect the consumers in all states and localities. Letter from Gale P. Gotschall, FTC Counsel for Federal-State Cooperation, dated January 4, 1976.

[82] *See* Cayne and Trebilcock, *Market Considerations in the Formulation of Consumer Protection*, 23 U. TORONTO L. J. 396, 426-27 (1973); Magnuson and Moss, *Current Federal Initiatives to Protect Consumers*, 10 GONZAGA L. REV. 319, 330-31 (1975). Testimony of Louis J. Lefkowitz, *supra* note 31.

Consumerism lives!

. . . and grows

by E. Patrick McGuire
CB Management Research

Several years back a news magazine, examining the state of religion in America, asked on its cover. "Is God Dead?" (*He* was not.) A few years later another magazine wondered, on its cover, whether consumerism was dead. (It *is* not.)

It has been the belief among many senior executives, however, that consumerism, if not yet dead, is certainly moribund. And the 1977 defeat of the Consumer Protection Act seemed to support that point of view. Indeed, Edie Fraser, president of Fraser Associates, one of the country's top consumer consulting firms, advised her corporate clients that "Carter Administration hopes for legislative consumer initiatives in 1977 have gone up in smoke. . . . No *major* piece of consumer legislation has been passed since the Magnuson-Moss Act and the Medical Device Act of 1976. . . .* Despite the leadership of consumer grande dame Esther Peterson, all the consumer organizations could not muster forces to overcome major opposition by business and many Congressional leaders."

But a new picture, obtained from a Conference Board survey of nearly 100 consumer affairs and customer relations executives and interviews with the directors of a number of consumer advocate organizations, indicates that the movement remains remarkably healthy—and influential. Consumerism, in fact, is here to stay.

How, then, have so many senior managements come to misjudge the situation? Consumer affairs managers believe it is because some business executives, despite all that has been written to the contrary, still view consumerism primarily as the expression of what is wanted by advocates—not by consumers as a class—and that these wants are translated into new legislation and regulations. Thus, in their minds, the legislative scorecard became all-important in assessing the strength of the movement. When the score declined—i.e., fewer laws, more emphasis on deregulation—they assumed that consumerism had spent its momentum.

Such a misperception bemuses some consumer affairs specialists. Mary Gardiner Jones—formerly an FTC commissioner, now a vice president of Western Union—says, "Some businessmen have never understood consumerism—perhaps never will. They just can't seem to grasp the breadth of the movement." Consumer affairs executives, however, know the truth of the situation.

These executives are confronted by an increasing number of customer complaints. Their legal departments, they report, are "inundated with lawsuits" by consumer plaintiffs. According to the results of the Board's survey, consumer affairs executives, by two to one, believe that consumer advocates are having an increasing impact on the public and government. And several major companies report that the number of customer complaints has jumped by more than 50 percent during the past two years.

Moreover, the number of Americans complaining to regulatory agencies has increased—in some cases, dramatically—over the past two or three years. Complaints to the Comptroller of the Currency about banking policies and practices have doubled in three years. Calls on the Consumer Product Safety Commission's hotline—a direct line for reporting or inquiring about unsafe products—have doubled in the last year. And the consumer complaint rate—complaints per population—has climbed notably at the Food and Drug Administration, Civil Aeronautics Board, Federal Trade Commission and other agencies.

Consumer advocates, because they are often among the first recipients of consumer complaints, are well aware that the tide of consumer dissatisfaction is still rising. But who are the consumer advocates, and what do they want?

Organizations include a dozen or more umbrella-type

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*The Magnuson-Moss Act, 1975, mandates the standards and performance of consumer warranties; the Medical Device Act regulates the testing and marketing of such equipment.

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groups—such as Ralph Nader's Public Citizen, The Consumer Federation of America, The Conference of Consumer Organizations, The National Consumer League—that tend to deal with a broad range of consumer issues, from financial services to truth in advertising. To a great extent, there is general agreement among these groups on various issues. On the other hand, there are many consumer groups that focus narrowly on specific issues, and their impact on business can be quite substantial.

GASP (Group Against Smoking and Pollution), for example, is concerned almost exclusively with smoking pollution and its reputed harm for nonsmokers. But this focus certainly affects many sectors of the economy other than cigarette manufacturers, particularly when government agencies decree that separate facilities must be provided for nonsmokers in planes, restaurants, trains. ACT (Action for Children's Television) concerns itself with advertisements aimed at young television watchers. But their efforts also reach the manufacturers of the products being advertised. And the impact on these companies may be more serious than that of some of the broader range advocacy organizations.

Consumer affairs executives like to stay in touch with those groups that have an influence on their companies' businesses, and about half of those surveyed say they make regular contact with them. Identifying consumer advocate organizations, however, isn't always easy. And simply concentrating on the "traditional" advocates won't fill the corporation's needs, since there is increasing evidence that organizations previously not thought of as "consumer advocates" are very much in the forefront of consumer issues.

Consider the American Association of Retired Persons (AARP), a group whose membership totals more than 12 million Americans over the age of 65. The AARP took on the issue of generic versus trade-name drug prescriptions. Although the over-65 members of our population account for only 11 percent of the total population, they purchase 25 percent of all the prescription drugs sold—more than $2 billion worth each year. By not having the option of substituting generic drugs for brand-name ones, they were paying more than they would have, had they been able to buy generic drugs. Unable to effect a change at the national level, AARP lobbyists adopted a grass-roots strategy and took their case to the state legislators.

The result? Since 1970 more than 40 states have adopted laws allowing—and in some states requiring—pharmacists to substitute generic drugs for brand names. Some companies, with a large investment in brand-name drugs, have fought an unsuccessful guerrilla war against AARP lobbyists. In terms of media visibility AARP may not rank with some of the Nader organizations, but it certainly has clout—ask the drug companies.

Also getting into the act are various health organizations—e.g., the American Heart Association, the Lung Association and the like. They may support the regulation—or even the abolition—of specific products or services, or urge government intervention on behalf of consumers in the sale and distribution of certain goods (such as artificial sweeteners).

And any attempt to identify the most influential consumer advocates must take into account certain government officials who perform advocacy functions. In the insurance sector, for example, Herbert Denenberg, former insurance commissioner for the state of Pennsylvania, is regarded as a pioneer in exposing insurance abuses and in drafting remedial action.

Or take California Gov. Jerry Brown, who joined such notables as Ralph Nader, Jane Fonda, Gray Panther founder Maggie Kuhn, and Dr. Benjamin Spock this past May in Washington, D.C., to participate in the antinuclear rally. The rally brought together an unlikely alliance of such groups as the Communist Party, the International Association of Machinists, the Union of Concerned Scientists, the Clamshell Alliance, the Gay Liberation Movement—if only momentarily—to protest nuclear power.

Jane Fonda and her husband, Tom Hayden, are in the forefront of the protest against nuclear power, and, in addition, advocate "consumer control of the massive corporations." Hayden, who helped found Students for a Democratic Society in the Sixties, heads a movement he calls the Campaign for Economic Democracy.

Despite the plethora of consumer advocate organizations, as well as corporate consumer affairs specialists, many dissatisfied consumers find they must eventually turn to the Federal government for assistance in resolving complaints. But the government's own studies show that the individual complainant is likely to receive short shrift from many, if not most, regulatory agencies.

Such was the finding of the Department of Health, Education and Welfare in a study of the handling of complaints by 22 Federal agencies during a two-year period, 1975-77. HEW reported that most of the agencies treated customer complaints as "general public correspondence," with no attempt made to analyze the data in order to use them to help formulate policy decisions.

In 1978 consultants again visited the agencies and found that almost two thirds were attempting to segregate complaints and handle them more systematically. But Esther Peterson, President Carter's Consumer Affairs Adviser, in announcing the results of this study also pointed out that the survey revealed that the agencies did not really provide much assistance to individual complainants. Indeed, the study itself concluded: "The Federal agencies in general exhibited weaknesses on a number of complaint-handling functions. Some of these weaknesses are due to government wide standard operating procedures and civil service regulations. Others are due to managements' failure to understand the importance of performing these functions effectively. This lack of awareness has resulted in the allocation of insufficient resources for the performance of many complaint-handling functions."

Several consumer advocates, when interviewed, wondered whether there is, in reality, a need to coordinate the government's complaint processing functions if the agencies aren't really doing anything for the consumer by helping to resolve individual complaints. As one Presidential aide explained: "In order to get a Federal agency involved in a complaint you have to be dealing with really big numbers. The agencies just don't want to fool around with an individual's complaint. They don't have the interest, or the resources. They want to take on whole industries, or deal with basic economic inequities."

One result of this situation is that many of the consumer advocates have become as disillusioned with government regulation as the business community has been. The picture that emerges from interviews with the advocates is that too many of the regulations are vague, unequally applied, arbitrary—even counterproductive. As a whole, they are *not* in favor of fueling the regulatory engine; some, in fact, believe that the nation has all the laws it needs to protect the health and safety of its citizens. It's not additional laws we need, these advocates say, but effective enforcement of existing laws.

> ❝The actions of advocates 'have made us more critical of ourselves, of the products we make, of the services we provide,' one appliance industry executive says.❞

"Laws work best only when people believe they will be enforced, and when the price of transgression is greater than the benefits obtained by violating the law," says one advocate. "But the problem is that when industry starts to disregard some of the most inane regulations, it is likely to be tempted to expand its disobedience into other areas, into laws and regulations that do directly affect consumers' health and safety."

But if regulations alone can't do the job, what other strategies are consumerists likely to espouse? The advocates interviewed favor a number of approaches.

Ralph Nader, who has had more than a few opportunities to observe "Federal policemen" in action (agencies such as the Consumer Product Safety Commission and the National Highway Traffic and Safety Administration), judges the regulators to be, often, more intractable foes than the companies he opposes. While it may come as a surprise to some of his adversaries, Nader continues to have considerable faith in a free (and responsible) enterprise system. It is his belief that a more rigorous enforcement of statutes that foster competition, such as antitrust laws, would go a long way toward correcting abuses that result from "product oligopolies"—dominance by a few suppliers.

Nader also subscribes to the theory that civil litigation—particularly the class action suit—is a powerful deterrent to corporate transgressions. Abuses of individual consumers, he points out, often amount to only a few dollars per customer. But millions of customers may be involved. He would like to see the rules of procedure changed to make it easier for class action suits to be filed in the Federal courts on behalf of consumers. And he would oppose significant alterations in tort liability statutes—such as a statute of limitations on claims or the use of state-of-the-art defenses—that would result in reducing the consumer's access to product liability litigation.

Arlie W. Schardt, former executive director of the Environmental Defense Fund, agrees with Nader that the best way to get something done is through litigation. The targets of the Fund's suits, however, are the regulatory agencies themselves. The Fund has been involved as a plaintiff in cases ranging from porpoise protection to Federal coal leasing—in suits aimed at getting Federal agencies to do what the law already empowers them to do. And the advocates point out that in some instances the agencies may actually welcome such suits. For a variety of reasons (including political considerations), regulators may be hesitant to enforce the letter of the law. But if an agency is sued and loses a court decision, it can evade the (political) responsibility of its activities by pointing out that their actions have been court-mandated.

In the early days of Carter's Presidency he promised to "out-Nader" Nader, and he appointed several consumer advocates to government posts, including Carol Tucker Foreman, former director of the Consumer Federation of America, who accepted a position as an under secretary in the Agriculture Department; and Joan Claybrook, an auto safety specialist and a Nader associate at Congress Watch, who was named to head up the National Highway Traffic and Safety Administration (both of whom escaped the Carter staff purge). These and other well-publicized appointments created the impression that the Carter Administration was actively pursuing a campaign designed to give consumerism power in various government agencies. The reality, consumer advocates say, has been quite different.

Of the 50-plus sub-Cabinet positions appointed by Carter, fewer than a half-dozen could be said to have bona fide credentials as consumer advocates. Many more individuals from business or academia have received such posts. And the track record—and influence—of those consumer advocates who have moved into the regulatory agencies is mixed. Indeed, a 1977 study by Common Cause found that regulatory agency executives consult business lobbyists "ten times more often than they do consumer representatives"—belying consumerist influence over regulatory decision-making.

A prescient Ralph Nader earlier had warned that, at best, consumer advocates would be less effective inside government and, at worst, they might be tied up and rendered impotent by the agencies they joined. In an interview Nader reiterated this point, and other consumer advocates tend to back him up. And since the defeat of the Consumer Protection Act, the Office of Consumer Affairs is now seen as being somewhat splintered, and, in the words of one observer, there seems to be "little real focus on any national issue."

Recently the president of an appliance manufacturer, vexed by attacks upon his company by consumerists, asked his consumer affairs director: "What conceivable good do they [the advocates] do? Wouldn't we have done many of the things that the advocates want, even if they weren't looking over our shoulders?" The answer, sadly, is no.

Most corporate consumer affairs specialists acknowledge that businesses would seldom have moved as fast—or as far—in improving their products. Several of the consumer affairs executives say that consumerism can produce significant dividends for the company that "works with it instead of against it." (Most agreed with this position, by more than 20 to 1.) The corporate specialists credit the advocates for helping in three prime areas:

1. Promoting improvements in product and service quality.

2. Helping to sensitize managements to the importance of consumer concerns.

3. Delineating the positions of consumers on various product, service, and economic issues.

Ned Smith, owner-relations manager at Ford Motor Company, while concerned with the inflationary impact that product regulations have had, says: "Their [the advocates] watchdog role, while sometimes painful, has resulted in measurable [product] improvement." And his counterpart at General Motors, customer-relations manager Glen Warren, agrees: "Consumer advocates have caused all manufacturers to do certain things that competitive pricing considerations would have otherwise precluded."

A recently published report from the Committee for Economic Development ("Redefining Government's Role in the Market System," a statement by the Research and Policy Committee, July 1979) points out that "although there is currently no accurate estimate of the overall cost of regulation, evidence about the cost of specific regulations shows that they are substantial." One of the conclusions drawn in the report—a conclusion that many senior managements would support—is that some of the goals sought by the government have "imposed enormous costs on the market system. Some of these costs have been borne by consumers and workers. The pursuit of unrealistic mandatory standards has therefore raised costs of production, reduced productivity, and contributed to inflation."

A majority of the consumer affairs executives surveyed believe that the actions of advocates have helped to make products safer and easier to use. "They have made u[illegible] more critical of ourselves, of the products we make, [illegible] services we provide," one appliance industry exe[illegible] says. The advocates are seen as providing one very [illegible]able contribution: a viewpoint not available from inside the corporation. "As hard as we try to market 'perfect' products," says Nell W. Stewart, director of customer relations at Texize, "we cannot always determine all of the possible effects of them in day-to-day use."

Perhaps one of the most significant areas of service improvement, according to the service executives, is in complaint handling. "Consumer advocates don't solve complaints," points out R.H. Janssen, director of consumer affairs for Culligan USA, "but they do force companies to take measures to solve individual problems."

It has even been reported that, in some cases, consumer advocates have more influence on senior managements than do the companies' own consumer affairs executives. Executives, understandably, are reluctant to be quoted on this point, but there are clear indications that outside pressure exerted by consumer activists has, at times, made the job of the consumer affairs executives an easier one to accomplish. "Management tends to procrastinate on some of my advice for improving service. But when an advocate or regulator gets interested in the area, management stops delaying and acts to correct the problem," says an airlines customer service executive.

The concerns and opinions of consumer advocates can also help clarify consumers' views and be a valuable source of market intelligence. While believing that advocates are occasionally "out-of-step with the consumers' interests," Coca-Cola vice president Dianne McKaig points out that "they are sometimes in the forefront of identifying issues . . . [and] it is useful to listen—and sometimes to act—on such subjects as a more comprehensive response to the consumer's right to know."

From the standpoint of both strategy and policy, companies may have more difficulty dealing with a grass-roots consumer movement than with one whose primary focal point is Washington, D.C. In fact, many of the companies surveyed say that local consumer advocate groups are often more important to them than some of the national organizations. Several of those questioned say that although their companies are national in scope, they now have to devote a major part of their resources to "fighting a brush fire in one state or region, rather than dealing with issues of national import."

This development, executives say, has significant implications for staffing the consumer affairs function, as well as for developing corporate responses to consumer issues. Companies may be more adept at responding to national issues than they are at coping with local ones, but the local issues can be just as influential on a firm's operations as the national ones. For example, companies that have committed substantial resources to the planning and development of production facilities at various sites around the country only to encounter stubborn local opposition to these plants—from local environmentalists, public interest groups, and so on—can testify to the importance of learning to deal with local issues.

Many professionals in the consumer movement, including the corporate consumer affairs managers, the advocates, and the regulatory agency staff members, expect that the movement will gain further strength in the early 1980s. There are certain issues that a majority of those surveyed expect to be of primary concern in the years immediately ahead:

☐ Public participation and intervention in regulatory decision-making, including public funding for such participation.

☐ Renewed pressure for the establishment of a Federal agency for consumer advocacy.

☐ Standards for complaint processing and settlement, including mandatory use of third-party arbitration.

☐ Measures to protect consumers against economic abuses such as utility cutoffs, invasion of privacy, credit discrimination, unfair debt collection, the continuing issue of unsafe products.

☐ More precise definition of the rights of consumers to sue for damages, with particular emphasis on easing the entry barriers to Federal class action suits.

☐ Deregulation of the trucking, communication, and insurance industries—and extension of the successful deregulation efforts at the Civil Aeronautics Board.

☐ Reform of antitrust statutes to allow consumers to recover damages from antitrust violations, and new legislation to inhibit conglomerate mergers.

Most of these issues can only be resolved at the Federal level. But some can be realized by state or county governments. First priority will be given to those issues that will effect cost reductions (i.e., tax savings), and it will come as no surprise to find that consumerists and business are once again at odds. But consumer advocates are beginning to realize that business is not a monolith—that it is often possible to find allies within the business community.

Action line

One phenomenon to emerge from the consumer movement over the course of the 1970s has been that of the action-line reporter. William Sklaar, a former Ralph Nader associate who is now a Washington attorney and consumer affairs consultant, put together a computerized list of action-line reporters.

"In the media, at least," explains Sklaar, "consumer issues have become an institution—a regular part of media coverage. And one of the reasons that editors regard it as such is the simple fact that there is a continuing source of news. There's been no substantive reduction in the number of complaints that find their way into the newsroom. And there are more than enough consumer abuses—some of them by 'reputable' companies—to pique the interest of both editors and their readers or listeners."

Media executives are well aware that action-line columns in newspapers or broadcast segments on TV news programs are high in reader or viewer interest. "They are another form of letters-to-the-editor," one newspaper editor explains, "and that has always been one of our best-read features." *The Chicago Sun-Times* recently completed a survey of its regular features and found that, next to the syndicated "Dear Abby" column, the action-line feature was the most-read part of its newspaper.

—E.P. McG.

As for companies, some have already perceived trends in the consumer movement and are moving in the same direction. Dwight Johnson, corporate consumer affairs specialist for American Telephone and Telegraph, says: "Companies are going to have to decentralize their consumer relations efforts. They're going to be even more dependent on consumer-conscious local managements. At AT&T we're trying to develop that kind of consciousness—and responsibility—at all levels of our company."

What happens to consumerism in a recession; is it put on hold? Looking back at previous recessions, one finds indications that consumer disaffection rises as economic activity falls. That makes sense. When people have less money to spend, their expectations about products and the services they do purchase tend to rise. But reality falls short of expectations—as it inevitably must. "We're hip deep in complaints right now," one appliance company executive said, "but the really high water is yet to come." ■

DEBATE PROPOSITION ONE

RESOLVED THAT: THE FEDERAL GOVERNMENT SHOULD INITIATE AND ENFORCE SAFETY GUARANTEES ON CONSUMER GOODS

In late 1972, Congress enacted one of the most comprehensive consumer measures in history--namely, the Consumer Product Safety Act. The Act provided for the establishment of an independent Consumer Product Safety Commission (CPSC) empowered to develop and enforce uniform safety standards for consumer products and to ban reasonably hazardous consumer products from the marketplace. Since its creation, the agency has come under wide-ranging criticism. Most of the critics feel that the Commission does not act quickly or efficiently, and that it does not try to compare benefits and costs in deciding where Government safety standards are necessary. A more general case is made by some that the CPSC experience is typical of well intentioned government intrusions into the market--costly, counterproductive, and inept. Proponents of government regulation for health and safety feel that it is one of government's most basic functions, namely, promoting the general welfare, and that the benefits derived far outweigh the cost of an agency such as CPSC.

The above proposition deals with the entire question of Government regulation, which involves more than the history of one particular Government agency. However, the scope of the CPSC and its actions to date illustrate much that the regulation question involves. The following articles provide background information on the CPSC, as well as other Government regulatory agencies, and look into the questions of safety, regulation, cost-effectiveness, and private enterprise.

The Consumer Product Safety Act—Its Impact on Manufacturers and on the Relationship between Seller and Consumer

By JAMES R. PATTON, JR.* and E. BRUCE BUTLER**
Washington, D.C.

ONE OF the most significant trends in the evolution of United States law with respect to the sale of goods has been the demise of a seller's power to limit his responsibilities to the purchaser or to subsequent purchasers for damage caused by the product sold.

A new phase in this evolution clearly has commenced, however, with respect to a limited, but nevertheless substantial, number of products. On October 27, 1972, the Consumer Product Safety Act became law.[1] Significant new restrictions under the Act eventually will be placed upon production and distribution of a large number of consumer goods. This article will describe the new law and attempt a preliminary assessment of its implications.

I. Evolution of Buyer Protection

The doctrine of *caveat emptor*, which often protected a manufacturer from responsibility for damage caused by his product, has been undercut steadily over the past century. Tort liability long has been recognized for injury arising out of the negligent manufacture, first, of inherently dangerous goods,[2] and then, of any product where a reasonable expectation of injury from such negligent manufacture existed.[3] Further refinements to simplify the burden of proof of negligence, such as the doctrine of *res ipsa loquitur*, have assisted an injured consumer in securing recovery.[4]

Contract law long permitted recovery under a warranty theory in those limited situations where privity of contract existed between the manufacturer and the consumer.[5] Contract warranty liability was extended a decade ago with the relaxation of the requirement of privity of contract.[6] The recent doctrine of strict liability in tort has further increased the injured consumer's

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[1] Pub. L. No. 92-573 (October 27, 1972).

[2] *See*, FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 5.02 (1971) and cases cited therein.

[3] MacPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916).

[4] FRUMER & FRIEDMAN, *supra* note 2, at § 12.03.

[5] *Id.* at § 5.01.

[6] Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960).

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ability to secure recovery from the manufacturer of a product causing injury.[7]

These developments all occurred at the state level. Each step was designed to compensate the injured consumer by increasing the consumer's ability to recover against the manufacturer of the product causing injury. At no time did the consumer have the right to restrain the marketing of hazardous products. Constitutional restrictions and limited resources restricted the extent to which states could regulate the distribution of hazardous products. By holding the manufacturer responsible for these injuries it was thought that the manufacturer would have a sufficient incentive to produce safer products.

The threat of adverse judgments and the supposed competitive disadvantage of unsafe products were not enough, however, to spur manufacturers to take the necessary preventive measures to avoid these injuries.[8] In addition, all of these remedies under state law require resort to the judicial process, with the attendant delays and expense. When the economic loss is small, a consumer's opportunity to recover is, in practice, quite limited. Because of these weaknesses of state law in dealing with product liability loss, federal regulation became inevitable.

II. Legislative History of the Consumer Product Safety Act

Federal concern with product safety started in earnest during the mid-1960's, although federal involvement in the market place through the imposition of requirements on sellers in the interest of safety existed occasionally prior to this time. The Food and Drug Act became law in 1906;[9] and the Flammable Fabrics Act was passed in 1953.[10] Several other laws covering hazardous products had been enacted prior to 1965.[11]

The present trend of federal involvement clearly began with the National Traffic and Motor Vehicles Safety Act of 1966.[12] This Act required the Secretary of Transportation to establish motor vehicle safety standards applicable to motor vehicles and related equipment. Sale of non-conforming vehicles or equipment was prohibited. Remedies under the Act included civil penalties and injunctions. Manufacturers were required to notify purchasers if certain types of defects were discovered.

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[7] Greenman v. Yuba Power Products, Inc., 59 Cal. 2d 67, 377 P.2d 897 (1963); RESTATEMENT (SECOND) OF TORTS § 402A.

[8] The National Commission on Product Safety has observed: "Despite its humanitarian adaptations to meet the challenge of product-caused injuries, the common law puts no reliable restraint upon product hazards." FINAL REPORT OF THE NATIONAL COMMISSION ON PRODUCT SAFETY 3 (1970). (Hereinafter REPORT.)

[9] 21 U.S.C. § 301 et seq. The Act was later enlarged to cover cosmetics.

[10] 15 U.S.C. §§ 1191 et seq. as amended.

[11] The Federal Inspecticide, Fungicide and Rodenticide Act of 7 U.S.C. §§ 135 et seq.; the Federal Caustic Poison Act of 1927, ch. 489, 44 Stat. 1406, repealed and replaced by the Federal Hazardous Substances Labeling Act of 1960, 15 U.S.C. §§ 1261 et seq. *See*, CONGRESSIONAL QUARTERLY SERVICE, CONGRESS AND THE NATION, vol. I at 1159-85 (1965) for a complete review of legislation during this period.

[12] 15 U.S.C. §§ 1381 et seq.

More than a half-dozen other laws followed in the succeeding five years, regulating poisonous packaging[13] the sale of products such as toys,[14] boats,[15] and household substances,[16] as well as radiation emissions from electronic products.[17]

In addition to this piecemeal approach to specific aspects of product safety, Congress created a National Commission on Product Safety in 1967 to study the problem in greater depth and to propose long-range solutions.[18] The National Commission held hearings on various aspects of the problem from October, 1968, to March, 1970, and issued its final report June 30, 1970. The National Commission was quite critical of existing Federal legislation, characterizing it as "burdened by unnecessary procedural obstacles, circumscribed investigative powers, inadequate and ill-fitting sanctions, bureaucratic lassitude, timid administration, bargain basement budgets, distorted priorities, and misdirected technical resources."[19] One recommendation of the National Commission was that an independent commission be created to establish standards for all hazardous consumer products.[20] A consumer safety advocate on the staff of the standard-setting agency also was strongly recommended.

The Commission rejected reliance on voluntary industry standards as "legally unenforceable and patently inadequate." Because of the necessity of a consensus among manufacturers for a voluntary program, the Commission argued that the least responsible segment of an industry could retard progress in reducing safety hazards.[21]

Legislation was first introduced late in the Ninty-first Congress, based upon a proposal prepared by the National Commission, to provide for an independent consumer product safety agency with authority to establish safety standards.[22] No action on the bill was taken during that session, however. Efforts at passage of this legislation were renewed early in the Ninty-second Congress.[23]

At the same time as the various bills regulating product safety were under consideration in the Ninty-second Congress, another piece of legislation had been introduced which would have created a consumer advocate, within the government.[24] This latter bill to create a consumer advocate who would have had only generalized authority to intervene and no authority to regulate, created significant opposition which ultimately succeeded in killing the bill.

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[13] Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471 et seq.

[14] Child Protection and Toy Safety Act of 1969, Pub. L. No. 91-113, 83 Stat. 187 amending the Federal Hazardous Substances Labeling Act.

[15] Boat Safety Act of 1971, 46 U.S.C. §§ 1451 et seq.

[16] Child Protection Act of 1966, Pub. L. No. 89-756, 80 Stat. 1303, amending the Federal Hazardous Substances Labeling Act 15 U.S.C. § 1261 et seq. *See*, Congressional Quarterly Service, Congress and the Nation, vol. II at 779-823 (1969) for a review of legislation during the period from 1965-1968.

[17] Radiation Control for Health and Safety Act of 1968, 42 U.S.C. § 263b.

[18] Pub. L. No. 90-146, November 20, 1967.

[19] Report, at 2.

[20] *Id.*

[21] *Id.*

[22] S. 4054 (June 1970).

[23] S. 983, introduced by Senators Moss and Magnuson; S. 1797, introduced on behalf of the Administration; and S. 3419 reported by the Senate Commerce Committee as an original bill (April 1972).

The product safety legislation, however, with specific provisions requiring extensive regulation of business, moved methodically through Congress and was passed by both houses in the closing days of the Ninty-second Congress. Although the bill contains much of the original National Commission proposal, significant changes were made in the House. The Act was signed by the President on October 27, 1972.

III. Provisions of the Consumer Product Safety Act

A. Structure

The Act establishes an independent commission, similar to the Federal Trade Commission or the Federal Communications Commission, which is charged with general responsibility for administering the Act. The National Commission's recommendation of an independent agency thus was adopted.[25] No provision is included in the Act, however, for a consumer safety advocate on the Commission staff.

One of the compromises necessary to secure passage of the bill was the elimination of foods and drugs from the jurisdiction of this new agency and retention of this jurisdiction in the Food and Drug Administration. Other existing product safety legislation, however, is transferred to the Commission, to be administered according to the terms of these acts rather than under the new law.[26]

The Commission was to be established immediately after enactment. The Act generally came into force on December 26, 1972, although certain functions were not to be transferred to the Commission until March 26, 1973, at the earliest.

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[24] S. 3970 would have established a Consumer Protection Agency to represent consumers before federal, state, and local agencies. The Senate failed to limit debate on this bill three times during the closing weeks of the Ninty-second Congress by only eleven votes, and thus the bill died without consideration on the Senate floor.

[25] Not only does the Consumer Product Safety Act (hereinafter CPSA) create an independent commission, but it grants the new commission autonomy from the executive branch generally, by providing (1) that the Commission's budgetary requests do not need Office of Management and Budget approval before submission to Congress and (2) that Commission testimony, recommendations or comments to Congress are not subject to prior executive branch approval, CPSA § 27(k).

[26] CPSA § 30. The functions of HEW, EPA, Department of Commerce, and the FTC under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970 and the Flammable Fabrics Act are transferred to the new Commission.

B. Product Safety Standards

The new Consumer Product Safety Commission is required to develop product safety standards for those consumer products which it determines to present an unreasonable risk of injury to the public.[27] The manufacture, distribution or importation of a product not in conformity with such a standard is prohibited. Standards promulgated under the Act can relate to the performance, composition, content, design, construction, finishing, or packaging of the product.

Under the procedure established by the Act, prior to the development of any product safety standard, the Commission is required to issue a notice indicating its determination that a safety standard is necessary to eliminate or reduce the risk of injury from a consumer product. The notice must contain information known to the Commission about existing standards and, in addition, must contain an invitation to persons interested in developing a standard for such product to submit to the Commission an offer to undertake such development.

The Commission then may adopt an existing standard issued by any Federal agency or by any other qualified body. In the event that no existing standard is adopted and that offers to develop proposed standards are submitted, the Commission is required to accept at least one of such offers if it determines that the offeror is technically competent and is likely to develop an appropriate standard within the required time. If no offer is accepted, the Commission then may develop its own standard.

The Senate version of the bill would have excluded manufacturers and other business interests from participating in the development of such standards.[28] The conference committee deleted this amendment from the Act and thus persons with a direct business interest in the product to be regulated clearly are entitled to participate in the development of standards under the procedures set forth in the Act.

The Commission is precluded from promulgating a safety standard or from authorizing the development of an alternative standard after it has accepted one offer to develop a standard. The final version of the bill does permit the Commission to work concurrently on a standard, however, when the only person offering to develop such a standard is a manufacturer, distributor, or retailer of the product for which a standard is being developed. It is not clear what the effect of Commission acceptance of an offer to develop a standard by a trade association representing these interests will be. From a policy standpoint, the Commission should be authorized to develop its own standard when the only offeror is a trade association, since this group's interest is identical to that of the manufacturers, distributors, or retailers acting individually.

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[27] It should be noted that the act applies only to *consumer* products, which are defined as an article or component part produced or distributed for sale to or personal use, consumption or enjoyment of a consumer in or around a household or residence, school or in recreation, CPSA § 3(a). Products intended for use primarily for industrial purposes are excluded, as are certain types of consumer products already subject to other regulatory legislation, such as tobacco, motor vehicles, economic poisons, boats, drugs, cosmetics and food.

[28] 118 CONG. REC. 9925-6 (daily ed. June 21, 1972).

The offeror is required to develop a standard pursuant to regulations and within a period of time set by the Commission. This period may not be more than 150 days after publication of the notice commencing the proceeding unless the Commission determines that there is good cause for this extension. The Commission may terminate development by an offeror if it determines that the offeror is unable or unwilling to complete its task within the period allotted. The Commission is required either to publish its proposed safety standard or withdraw its notice of proceeding within 210 days of publication of the notice of a need for such standard unless this period is extended by the Commission for good cause. Thus, if the Commission is dissatisfied with a standard developed pursuant to its acceptance of an offer, it could extend the time period and proceed to develop its own standard.

The Act requires the Commission to hold a rule-making proceeding, affording an opportunity for oral presentations, before it promulgates a standard. The Commission must consider a number of factors before it can promulgate the regulation, such as the degree and risk of injury, the need of society for the product, the effect of a standard on the utility, cost and availability of the product, the number of products which would be subject to the rule, and the means of achieving the public health and safety objective with minimum adverse effect on competition or the disruption or dislocation of manufacturing or other commercial practices. In addition, the Commission's determination to promulgate or withdraw a standard is subject to judicial review. Persons having standing to seek judicial review include anyone adversely affected by a rule, and specifically include a consumer or consumer organizations.

In addition, the Commission is empowered to seek a court order to have a product declared imminently hazardous even during the course of its standard-making procedure or despite the fact that a standard for the product exists. The Commission can request the court to order either temporary or permanent relief, which may entail seizure, public notice of the hazard, or recall, replacement, repair, or refund with respect to the product.

C. Effective Date of Standards

The effective date of any standard promulgated by the Commission may not be more than 180 days nor less than 30 days after the date of promulgation, unless the Commission determines that there is good cause for extending or reducing the period before the standard is to become effective. In no case, however, may the standard be made retroactive to a date prior to promulgation.

The Commission is authorized to prohibit stockpiling of a product between the time of promulgation and the effective date of a standard. In order to determine whether illegal stockpiling has occurred, the Commission is required to establish a base period for the product prior to promulgation of the standard and to prohibit manufacture or import of a product at a rate significantly greater than this base period.

D. Certification and Labeling

Every manufacturer of a product subject to safety standard is required to certify that the product complies with such standard. Any certification given must be based upon a reasonable testing program.

The Commission further is authorized to require labels setting forth in detail a number of items about the product, including warnings regarding the product and the date of its manufacture. No product may be imported into the United States unless it complies with applicable certification and labeling requirements. Provision also is made for certification and labeling by private labelers rather than the actual manufacturer. In this situation, the private labeler assumes the responsibilities of the manufacturer under the Act.

E. Remedies

Any manufacturer, distributor, or retailer who determines that a product fails to comply with an applicable consumer safety standard or that the product contains a defect which could create a substantial risk of injury must report this fact to the Commission.

The Commission, after an informal hearing, can require the manufacturer, or any distributor or retailer, to give public notice of any defect creating such a risk of injury or of failure to comply with an applicable standard and to mail such notice to other manufacturers, distributors, retailers, or consumers.

If the Commission determines that a substantial product hazard exists because of the risk of injury or because of failure to comply with a standard, it may compel the manufacturer, distributor, or retailer, at such businessman's option, to repair, replace, or refund the purchase price for any particular product.

F. Inspection and Record-Keeping

The Act obligates manufacturers, distributors, and retailers to permit inspection of their facilities to determine compliance with the Act. In addition, it requires manufacturers, private labelers, importers, and distributors to maintain such records as the Commission shall require for purposes of determining compliance. Retailers are specifically exempted from any record-keeping requirements because of the burden which would be placed on them if records were required.[29]

G. Preemption

The Act prohibits states or municipalities from establishing safety standards which are not identical to federal standards. Preemption thus exists only with respect to products subject to a federal standard.

States and political subdivisions are given the right to petition the Commission to exempt a local standard from the preemption clause if the state can show that the state standard imposes a higher level of performance than the federal standard; that this higher state standard is required by compelling local conditions; and that the state standard does not unduly burden interstate commerce.

H. Exports

Products destined for export, and which are so labeled, are not required to comply with federal standards.

I. Ban on Hazardous Products

The Commission is granted authority to ban further distribution of a product if it determines that the product presents an unreasonable risk of injury and that no feasible product safety standard would adequately protect the public.

J. Enforcement

Numerous methods of enforcement are provided under the Act. A knowing violation of the prohibitions contained in the Act subjects the person to civil penalties of up to $500,000. If the violation is willful as well, criminal penalties may be imposed. Injunctive relief against further distribution or seizure of goods already in commerce may be sought in U.S. district courts by the Commission (with the concurrence of the Attorney General) or by the U.S. Attorney General. Any interested person may seek injunctive relief to enforce safety standards and may recover a reasonable attorney's fee. A private right to damages for loss by reason of a knowing violation of a safety standard is created under the Act.

K. Miscellaneous

The Act provides for the creation of a Consumer Product Safety Advisory Council, which the Commission may consult, but is not required to consult, at any stage in its proceeding. The Advisory Council is to be composed of five governmental representatives, five industry representatives, and five consumer interest representatives. The Council is authorized to propose consumer product standards to the Commission.

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[29] H.R. Rep. No. 1153, 92d Cong., 2d Sess. 44 (1972); H.R. Rep. No. 1593, 92d Cong., 2d Sess. 54 (1972).

In addition to the authorization for private petitions for injunctive relief against manufacturers violating an applicable product safety standard, private parties are permitted to petition the Commission to commence a proceeding leading to the issuance, amendment, or revocation of a consumer product safety standard. Judicial review is provided in the event of denial of such a petition, but only for petitions submitted after the Commission has been in operation for three years.

The Act also requires the Commission to maintain an injury information clearinghouse to coordinate the gathering and dissemination of information on injuries, to undertake studies and research, and to test products and develop testing methods and devices. The Commission can require that a manufacturer turn over to it technical data with respect to the performance and safety of a product and can require that the manufacturer disclose this information to consumers.

IV. The Significance of the Consumer Product Safety Act

The Act is one more step in the pervasive federal regulation of all aspects of industrial activity brought on by the increasing demands of society for governmental protection from those detrimental activities damaging the quality of life. The Occupational Safety and Health Act regulates in detail the manner in which industrial activity is to be carried on within the plant.[30] The Clean Air Act of 1966[31] and the Water Pollution Act of 1972[32] regulate the manner of waste disposal from industrial activity. The Noise Control Act[33] creates procedures for the establishment of permissible noise emission levels for all types of products.

The Consumer Product Safety Act now provides for regulation of the structure of a significant number of products manufactured or imported into the United States. Although the Act limits the Commission jurisdiction to consumer products which present a risk of death, personal injury, or serious or frequent illness, the number of products included still will be significant.[34] The experience of manufacturers under other safety legislation, particularly the National Traffic and Motor Vehicle Safety Act,[35] indicates that this regulation will create significant additional expenditures and could make the continued manufacture of some products difficult, if not impossible.

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[30] 29 U.S.C. §§ 651 et seq.

[31] 42 U.S.C. §§ 1857 et seq., as amended.

[32] Pub. L. No. 92-500 (October 18, 1972), replacing several prior acts, the Water Pollution Control Act of 1956, the Water Quality Act of 1965, the Clean Water Restoration Act of 1966, and the Water Quality Improvement Act of 1970.

[33] Pub. L. No. 92-574 (October 27, 1972).

[34] The National Commission on Product Safety listed 200 products which it believed to present serious risks of injury.

[35] The Department of Transportation has issued numerous complex standards under the Traffic and Motor Vehicle Safety Act, 49 C.F.R. § 571.

In addition to these significant obligations with respect to the manufacture of a product, the Act imposes new and extensive obligations on the manner in which business must operate. The Act also adds a new dimension to the relationship of buyer and seller and will undoubtedly have some effect on product liability litigation. One other important aspect of this legislation is the extent to which both business and consumer groups are drawn into the regulatory process and are given an opportunity to shape safety regulations at all stages in the proceedings.

A. Impact on the Manufacturing Process

Clearly, the most dramatic impact of this new legislation will take place in the manufacturer's plant. The design of numerous products, in time, will be required to conform to new Federal standards. In some instances, these designs may not be feasible for certain manufacturers. Product lines may be required to be altered drastically and, in some extreme situations, even dropped. Other products will be banned totally as being too hazardous. No requirement exists that a standard be economically reasonable, although the procedure requiring acceptance of offers to develop standards will result in consideration of feasibility in all instances where manufacturers are participating in the development of the standards.[36] The Commission is required to consider and make findings with respect to the impact of its action, but, nevertheless, is empowered to promulgate its proposed standard even if the economic effects will be significantly adverse. The only restriction on the Commission is that the standard be reasonably necessary to eliminate or reduce an unreasonable risk of injury. The House Commerce Committee indicated that it expected the Commission to balance the risk and gravity of harm against the utility, cost, or availability of a product in determining whether the hazard presents an unreasonable risk.[37]

New products may take on increased importance and value if standards require their use. Since standard specification of the components to be used can create dangers and difficulties of governmental involvement in business planning, the Act requires the Commission, whenever feasible, to develop performance standards rather than product specifications. Performance standards clearly are desirable because they permit the manufacturer to achieve the required performance level by any competitive means, thus securing the desired protection without limiting the manufacturer's discretion in the method of achieving the desired result.

New labels and warnings may have to be added to products and new packaging developed. Conforming with these requirements will involve minor design problems. Labels which contain the date of manufacture can create production, distribution, and marketing problems because of consumer demand

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36. See, for example, § 6(c)(1) of the Noise Control Act of 1972, Pub. L. No. 92-574, where one of the criteria in establishing a standard is the cost of compliance.

37. H.R. Rep. No. 1153, 92d Cong., 2d Sess. 33 (1972).

for products manufactured as near to the date of sale as possible. To avoid this "open-dating" problem, the Commission is authorized to permit manufacturers to code this information.[38]

The Act contemplates that most standards will become effective within a period of 30 to 180 days after their promulgation. Since goods on which manufacture is not completed prior to the effective date will be covered by a standard, manufacturers that need a long lead time to comply with the requirements of such standard either (1) will have to anticipate promulgation and make necessary changes while the standard is under development or consideration by the Commission, or (2) will have to seek extension of the period before the standard takes effect.[39] This problem can be particularly acute for importers. Products manufactured before the effective date still may be exported to the United States unless the Commission, after a hearing, determines that the product contains a defect which creates a substantial risk of injury to the public. Products manufactured after the effective date of a standard and not in compliance with such standard may be imported under bond provided the products are brought into compliance before distribution in the United States.

One of the few clear benefits to manufacturers which may result from the Act is that the problems created by varying state product safety standards will be eliminated in many cases. The Act contains a strong preemption clause, which prohibits states from establishing safety standards which are not identical to those established at the federal level. The Act does not prohibit state activity, however, until federal standards have been established.

B. Impact on the Manner of Doing Business

The new legislation clearly will result in increased costs of doing business as the result of the new obligations imposed on manufacturers, distributors, and retailers. The Commission can require businessmen to keep extensive records showing compliance with the Act. The extent to which manufacturers and distributors will have to maintain lists of purchasers under the Act is not clear. It may be that manufacturers will fulfill this requirement simply by maintaining a list of warranty cards, although the percentage return of these cards in many industries is traditionally low. If the manufacturer does not have a suitable list of purchasers, however, the probability that it will be required to give a generalized public notice, with all the attendant adverse publicity, increases. The House Commerce Committee report indicates that if certification information is coded, the manufacturer's or private labeler's obligations to give adequate notice will be greater.[40] The exemption of retailers from record-keeping requirements greatly increases the difficulty for manufacturers and distributors to establish their own lists of purchasers. Since the Commission is required to afford interested persons, including consumer groups, with an opportunity to comment on whether notice should be given, some adverse publicity will occur in any case where the issue either of a failure to comply with a standard or of the existence of a hazardous product defect is raised.

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[38] CPSA § 14(c).

[39] Manufacturers may be forewarned of possible Commission action. The House Commerce Committee Report states that it expects the Commission to inform manufacturers about potential safety hazards as it develops information on products. The Committee indicates that it hopes that manufacturers will act to cure the problem without resort to the standard procedure, H.R. Rep. No. 1153, 92d Cong., 2d Sess. 30 (1972).

Additionally, manufacturers and consumer protection groups will have to maintain a concern for the progress of safety standard development. Manufacturing groups may continue to develop voluntary standards, although such industry standards are subject to the antitrust laws. The Federal Trade Commission has published guidelines with respect to industry standards.[41] Among these guidelines is the requirement that the public participate in the development of the standards.

Independent standards-making groups such as American National Standards Institute, which is a federation of the principal standards-making organizations in the United States, and private testing laboratories, such as Underwriters Laboratories, will play an increasingly significant role under the new legislation. Public participation in the proceedings of these groups also is required under the Act.

A manufacturer of a product which is subject to a safety standard, and thus is required to certify compliance with this standard, is also required to maintain a reasonable testing program upon which its certification is based. The Commission is granted authority to prescribe this testing program. Testing may be done by qualified independent third parties.

Manufacturers may be required to give notice to the Commission prior to the introduction of new products into the market. The Commission may not require pre-market clearance before these products can be distributed, however.[42] The procedures for this pre-distribution notification will be established by the new Commission. The Commission also can require that products be marked with, or accompanied by, clear and adequate warnings or instructions, and can prescribe the form of this warning or instruction.

The Commission may require a manufacturer to maintain technical data related to the performance and safety of the product and can require that this information be given to consumers purchasing a product. The Commission also is empowered to require manufacturers to make reports to it and to secure other information through its own research. Manufacturers will have to be alert to Commission release of information and may have to file formal comments to prevent disclosure. The flow of information to the public with respect to a specific manufacturer or its products may be significant.

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[40] *Id.* at 41.

[41] Reprinted in CCH TRADE REG. REP. ¶ 1718.20.

[42] H.R. REP. No. 1153, 92d Cong., 2d Sess. 39 (1972).

The Federal Trade Commission has issued three recent proposed complaints which relate to product safety labeling and the manner in which products may be advertised.[43] The complaints in those cases allege that advertisements promoting the safety or hazard-free nature of the products are deceptive as proven by the warning labels on the product. In addition, the FTC alleges that the advertisements are unfair or deceptive because they detract from the effectiveness of warnings or instructions on the products.[44]

C. The Manufacturer's Obligation to Consumers

Federal law is changing significantly the role of the warranty in establishing a manufacturer's obligations with respect to defective products. Doctrines such as strict liability in tort have developed at the state level to prevent limitation of a manufacturer's obligations *after* a defective product has caused injury. The new Act now increases the manufacturer's obligations to consumers *before* they have been injured.[45]

If a product fails to comply with an applicable standard or creates a substantial risk of injury (even though no standard has been promulgated), a manufacturer, distributor, or retailer is required to notify the Commission of this failure to comply or risk of injury. A consumer also may bring the matter to the Commission's attention. In either case, the Commission must hold hearings before determining that a substantial hazard exists. This proceeding provides the manufacturer with an opportunity to present its case that the remedies set forth under the Act are not required. Once a determination is made that a substantial hazard exists, the Commission can require that the manufacturer give notice of the defect publicly or to each purchaser of whom it has knowledge. The House Report indicates that this notice must be actual notice and that a manufacturer will not be required to go through retailer records to develop a list of purchasers.[46]

In addition to requiring this notice, the Commission also is empowered to require the manufacturer, at the manufacturer's option, to repair the product, to replace it, or to refund to the consumer the purchase price for the product, less a reasonable allowance for use if the product has been in the consumer's possession for more than a year after notice of the defects is made public or acquired by the consumer. Similar requirements also can be imposed on distributors or retailers.

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[43] Proposed complaints issued to Hercules, Inc., Union Carbide Corp., and FMC Corp, CCH TRADE REG. REP. ¶ 20,131 (Nov. 1, 1972).

[44] *See*, FTC v. Sperry Hutchinson Co., 31 L. Ed. 2d 170 (1972) for a discussion of FTC authority to challenge unfair trade practices.

[45] Additional legislation which would have reduced further the freedom of manufacturers in issuing warranties was introduced during the Ninty-second Congress, but did not pass, S. 986. This bill provided specific definitions for full and partial warranties and would require each warranty to be labeled as "full" or "partial."

[46] H.R. REP. No. 1153, 92d Cong., 2d Sess. 42 (1972).

No charge is to be made to any consumer who avails himself of a remedy under this provision. In addition, the consumer is to be reimbursed for any reasonable and foreseeable expenses incurred in availing himself of the remedy. Thus, for example, any shipping costs incurred by the consumer in returning a defective product may have to be borne by the manufacturer, distributor, or retailer. The Commission also may order reimbursement by one manufacturer to other manufacturers, distributors, or retailers for their expenses incurred in carrying out a remedy required pusuant to this Act. The Commission can require that a plan for taking the required action be submitted to it for approval before it is implemented.

The Act requires that a new written warranty be given to consumers. This is a certification that the product complies with applicable product safety standards. Any consumer injured by reason of a knowing violation of a safety standard may sue in federal court. Such a litigant is entitled, in the discretion of the court, to recover reasonable attorney's fees. The Act specifically disavows any limitation on private litigation remedies. Thus, proof by a manufacturer that its product is in compliance with a federal standard may not be proof of due care. State law still may impose a higher duty of care on the manufacturer. Violation of a safety standard, however, may be held as negligence *per se* in many states.

The Act will have a further effect on private injury litigation because significantly greater amounts of data will be available to both parties to the litigation through the Injury Information Clearinghouse to be established within the Commission. Commission files presumably will include material as to the cause of various accidents, as well as test-results with respect to products. Commission investigative reports on specific accidents will be available to the public. Public availability of information assembled by the Commission will be restricted only if the information contains trade secrets, confidential statistical data, or other matter entitled to confidential treatment. A procedure is established under the Act whereby a manufacturer is entitled to challenge the Commission's intended release of information before the actual release is made.

D. New Relationships in the Regulatory Process

The Act continues a trend developed in the forerunners to the present comprehensive consumer product legislation—the use of an advisory council composed of public, consumer, and industry members to consult with the Commission during the regulatory process.[47] The role of the advisory council may be significantly less important under the product safety act than has been true under other legislation because the Commission is not required to consult with the council but has complete discretion with respect to such consultation. These councils can be of significance in developing regulations because they afford both the consumer and business interests with an opportunity to assist in shaping regulations at an early enough stage in the proceedings so that changes can be made with relative ease and without delaying the regulatory process.[48]

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[47] *See*, the Motor Vehicle Safety Act, 18 U.S.C. § 1393; the Boat Safety Act, 46 U.S.C. § 1482; the Clean Air Act, 42 U.S.C. § 1857 (c); and the Occupational Safety and Health Act, 29 U.S.C. § 656.

The requirement that the Commission accept an offer to develop a standard if no existing standard is considered adequate insures that most standards will be developed outside the government. This lessens the budgetary impact of this new program, but is done at the expense of control over standards development. Since industry often already is working closely with those organizations most likely to submit an offer to develop a standard, industry input in establishing standards is assured. Because of the importance which these standards-making organizations are granted under the Act, consumer and public participation in these deliberations undoubtedly will increase. The Act requires that consumer groups be given notice and the opportunity to participate in the development of standards. The Commission may contribute to the costs of an offeror to assure public participation in the standard development process.

In addition, consumer interests are given a right of intervention to enforce existing safety standards. Any interested person, including consumers or consumer organizations, is permitted to petition for the issuance of a product safety standard. The Commission is required to act on this petition within 120 days. If such petition is denied, petitioners eventually will be able to seek judicial review in a de novo hearing on the question of whether the requisite risk of injury exists. Judicial review is not authorized for three years after establishment of the Commission in order to permit the new body to establish its priorities.

All proposed standards are subject to the informal rule-making procedures permitted under the Administrative Procedure Act,[49] rather than the more formal hearing procedures, such as those utilized by the Food and Drug Administration, which require a written record and the opportunity for cross-examination of witnesses.[50]

V. Conclusions

This preliminary assessment of the Consumer Product Safety Act describes only the legislative framework for regulation of numerous products. The manner in which the new Commission carries out its mandate will depend on numerous factors, including the vigorousness with which the new Commissioners move to regulate; the responsiveness of industry and consumer interest groups to the standard-making procedures; and the resources granted to the Commission for its staff and facilities. Regardless of the extent to which these factors vary, the existence of this Act, in itself, will have a significant impact on business operations.

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[48] See the Federal Advisory Committee Act of 1972, Pub. L. No. 92-143, § 10 (October 6, 1972) for procedures required of all federal advisory committees. These procedures generally are designed to insure that the proceedings of advisory committee deliberations are public information.

[49] 5 U.S.C. § 553.

[50] 5 U.S.C. §§ 556-7.

ECONOMICS OF LIFE AND SAFETY

Consumer Product Safety Regulation

By Henry G. Grabowski and John M. Vernon*

Government policy toward consumer product safety has experienced major institutional changes in the United States over the past fifteen years. In particular, Congress has passed a number of laws imposing and strengthening federal regulatory controls on product safety across a broad spectrum of markets.

In the food and drug area, the 1962 Kefauver-Harris Amendments made the premarket approval process for new pharmaceuticals much more stringent and extended Food and Drug Administration (*FDA*) controls over the pharmaceutical research and development process. The 1968 Delaney Amendments required the *FDA* to ban any food additive from the marketplace found to be carcinogenic in animals, regardless of foregone benefits. The 1976 Medical Device Amendments extended *FDA* controls to all medical devices (for example, heart pacemakers, cardiographs, stethoscopes, etc.) and many classes of medical devices will now be subject to a premarket approval process similar to that for new drugs.

Beginning in the mid-1960's, Congress also has passed a succession of product safety laws dealing with specific products such as automobiles, toys, flammable fabrics, lead-based paints, and poisonous and toxic substances. Most of these responsibilities were eventually consolidated and put under the jurisdiction of the Consumer Product Safety Commission (*CPSC*), created in 1972. This new agency was given a broad mandate by Congress to set safety standards for all consumer products presenting undue risk of injury, except for those products already regulated by an established agency (for example, food, drugs, pesticides, and autos).

Thus Congress has extended federal product safety controls to virtually all areas of the marketplace. While it is too early to evaluate the impacts of this new regulation, it is possible to make some general observations about its emerging characteristics.

First, in drafting and funding new product safety legislation, Congress has strongly favored direct regulatory controls (for example, product standards, premarket approval, prohibitions of very risky products, etc.) compared to other policy instruments that might be employed to encourage greater product safety. In particular, two alternatives often advocated in the academic literature—the generation and dissemination of better information about product safety hazards and the use of economic incentives (i.e., taxes or subsidies) have been given little attention.

Second, the decision-making process at the various agencies appears to embody a strong "safety imperative." That is, there is strong resistance to the notion that the benefits of greater safety stemming from a particular policy must be weighed against the costs that might be entailed by that policy. To a considerable degree, the regulatory agencies are probably reflecting the desires of Congress in this regard. The product safety laws tend to be drawn with very specific and narrow mandates (for example, to protect consumers against unsafe products) and provide few incentives for agency decision makers to introduce cost considerations into their decisions. While it is true that these agencies are now required to calculate "economic impact" or benefit-cost analyses of their decisions, these generally take on an "after the fact" character. As we show in our analyses of the *CPSC* and the *FDA* below, the results of benefit-cost analyses apparently have little effect on regulatory decisions.

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Third, there currently exists little effort to design regulatory policies so as to complement existing market and legal incentives regarding product safety. Presumably the rationale for government regulation of product safety rests first on the presence of market information imperfections, and second, on the fact that the tort liability system (which makes producers liable for "defects" in their products) provides weak incentives in many circumstances because of high transactions costs and uncertainties in legally determining fault. However, these market and legal imperfections vary greatly across different product areas and industry categories. Therefore, in setting priorities for regulatory action, an agency with broad discretionary powers like the *CPSC* should presumably concentrate on those areas where market and legal incentives for product safety are most deficient. In this way they can target their resources to the areas where potential benefits are greatest relative to costs.

Fourth, product safety standards and regulations can result in significant unintended side effects on the long-term competitive structure of an industry. Our own recent analysis of the pharmaceutical industry, for example, indicates that increased regulation since 1962 has resulted in a much greater concentration of innovation among the largest drug firms. Similarly, recent analyses of the *CPSC* proposed standards in power lawnmowers indicate that implementation of these standards would eliminate several small producers and significantly increase industry concentration (see W. Brockett et al.).

In the remainder of the paper, we specifically analyze the behavior and performance of the two principal agencies engaged in product safety regulation (the *CPSC* and the *FDA*) and consider these points in more detail.

I. The Consumer Product Safety Commission

Congress passed the Consumer Product Safety Act in 1972 which created the *CPSC* and empowered it to "protect the public against unreasonable risks of injury associated with consumer products" (*CPSC*, 1976). It has been estimated that the Commission has jurisdiction over some 10 to 11 thousand different products which account for about $750 billion in annual sales. Among the policy options which the Commission has to carry out its mandate are the dissemination of information, the development of minimum safety standards, and the outright ban of especially hazardous products.

To date the Commission has proposed or implemented safety standards for products such as bicycles, matchbooks, power lawnmowers, swimming pool slides, and public playground equipment. In establishing priorities on standards, the Commission has relied heavily on its frequency severity index of product related injuries. This is based on the number and character of injuries from a particular product class recorded at hospital emergency rooms.

This approach to establishing agency priorities has been strongly criticized in a recent study by Nina Cornell, Roger Noll, and Barry Weingast. In particular, they argue that while the products targeted for standards by the *CPSC* have above average injury rates, they are products involving risks which are well understood and voluntarily assumed by consumers. At the same time, the Commission has given little attention to more sophisticated products like microwave ovens, where the hazards are more subtle and less clearly defined and for which information on safety characteristics is more difficult for consumers to obtain. This type of product, of course, rarely shows up as the cause of emergency room injuries, but may pose significant long-run health hazards about which there is general consumer ignorance.

In our opinion, a major ongoing problem with the *CPSC* approach to product safety regulation is that it does not really try to compare benefits and costs in deciding where government safety standards are necessary. Rather, the Commission's decisions reflect a "safety imperative" which tends to ignore the cost side of the equation almost completely. This is demonstrated by an analysis of the priority rankings for forty-six product classes which are considered in the *CPSC Mid-Year Review* (March 1977). This report suggests various factors and criteria as relevant to establishing Commission priorities including the frequency and severity of injuries, causes of injuries, costs and benefits of *CPSC* action, unforeseen nature and vulnerability of the population at risk, the probability of exposure to hazard, and other factors.

Table 1 presents the rankings and corresponding benefit-cost ratios for twenty-one product classes for which ratios were available. Although many of these benefit-cost ratios are based on very preliminary economic analyses, they are the numbers available to the staff and commissioners in establishing priorities. The priority rankings refer only to the Commissioners' ordering of the twenty-one products in Table 1, and not their rankings among all forty-six products that they evaluated. However, rankings 1–12 in the table were all accorded the status of "high priority" and are targeted for standards by the *CPSC* during the coming year.

TABLE 1—*CPSC* PRIORITY RANKINGS AND BENEFIT-COST RATIOS OF CURRENT AND FUTURE PROJECTS

Project	Benefit-Cost Ratio	Priority Ranking
Bathtubs and Showers	2.70	12
Over-the-Counter Antihistamines	2.52	15
Public Playground Equipment	2.02	3
Gas Space Heaters	1.85	2
Drain Cleaners	1.08	17
Ladders	.94	11
Glazing Materials	.91	4
Ranges and Ovens	.87	7
Trouble Lights	.75	8
Chain Saws	.67	14
Upholstered Furniture	.48	5
Power Saws (portable)	.40	13
Power Mowers	.40	1
Matches	.37	10
Rust Remover	.34	20
Petroleum Distillates	.25	16
Power Saws (nonportable)	.16	18
Ammonia	.11	21
Extension Cords	.10	8
Television Sets	.09	6
Wearing Apparel	.02	19

Source: Benefit-cost ratios were obtained directly from a *CPSC* Bureau of Economic Analysis staff memorandum or calculated from new or revised data supplied in the *CPSC Mid-Year Review* using the procedures of the *CPSC* Bureau of Economic Analysis; priority rankings were obtained from a *CPSC* News Release.

It is clear from Table 1 that the *CPSC* does not accord great weight to benefit-cost analysis, either in the absolute sense of the desirability of pursuing the project at all or in the ranking of projects. Only five projects of the twenty-one have ratios exceeding unity. Furthermore, the number one priority ranking in the table, power mowers, was ranked second by the Commissioners out of forty-six and it has a benefit-cost ratio of only .40 (total benefits were estimated at $112 million compared to costs of $285 million).

In doctoral dissertation research currently underway, Lacy Thomas is analyzing the *CPSC* decision-making process. His effort is directed at determining empirically the implicit weights for project attributes that the *CPSC* uses in establishing its choices among projects. Using a logit analysis, Thomas has found that estimated benefits (which are highly correlated with the estimated frequency and severity of injuries for each product class) dominate cost considerations in the setting of agency priorities. In particular, estimated coefficients on the benefit variable are ten to twenty times larger in absolute magnitude than those on the cost variable.

It should be noted that *CPSC* members and other product safety regulators have argued that there are very good reasons for not making their decisions depend directly on the outcomes of benefit-cost analysis. First, they suggest there is no generally accepted operational methodology among economists for valuing human lives. Second, they point out that the benefits and costs are not comparable. The benefits involve the saving of human lives and the reduction of bodily injuries and health hazards while the costs involve higher product prices, lower business profits and other "economic" effects.

While these arguments are apparently quite persuasive to many congressmen and consumer advocates, at best they only argue against the use of a strict benefit-cost criteria of unity in accepting or rejecting a project. It is still appropriate to use some type of benefit-cost calculation in ranking projects and setting priorities, if the Commission's actions are to be *cost effective*. The rankings in Table 1 obviously do not have this property. In effect, they would seem to imply that the benefits of saving lives or preventing injuries for a product class like television receivers or extension cords (which are given high priority but have very low benefit-cost ratios) are worth several times more than the corresponding benefits obtainable from product classes like chain saws or drain cleaners (which have much higher benefit-cost ratios but are given considerably lower priority by the Commission).

The utilization of benefit-cost analyses in this manner would also seem to have advantages in helping the Commission to choose among alternative strategies of government intervention. There may well be cases, for example, for which safety standards have a relatively higher benefit-cost ratio but where some alternative strategy (for example, information dissemination) could accomplish the same objective in a more cost efficient manner. While the Commission and Congress have tended to favor safety standards over other strategies, at present they cannot justify these preferences on cost efficiency grounds since the requisite benefit-cost analyses have never been undertaken.

II. FDA Regulation of Pharmaceuticals and Medical Devices

In contrast to the recent charter of the *CPSC*, government regulation of pharmaceuticals started in 1906 and has evolved over time into a very stringent system of premarket controls over new drug development and introduction. While early regulation was oriented at patent medicine abuses, the sulfanilamide tragedy in 1938 led to passage of the Food Drug and Cosmetic Act which required *FDA* approval of all new drugs as "safe" before they could be marketed. Then in 1962, as the disastrous effects of thalidomide were becoming apparent in Europe, the Kefauver-Harris Amendments were passed. This law expanded *FDA* controls to the clinical testing and development process for new drug compounds. In addition, manufacturers were required to demonstrate the therapeutic efficacy as well as safety of a new drug to obtain *FDA* approval.

The fact that new drugs can be the source of serious unforeseen toxic side effects in addition to strong therapeutic benefits justifies these strong regulatory controls in the minds of many individuals. At the same time, *FDA* regulatory decisions have been characterized by an extreme form of safety imperative. As *FDA* Bureau of Drugs director Richard Crout has indicated: "I would emphasize very strongly that the Food and Drug Administration regulates health policy, not economic matters. That is terribly important to understand. We do not pay any attention to the economic consequences of our decisions and the law does not ask us to" (pp. 196–97).

Over the period since the 1962 Amendments were passed, a number of adverse trends have been observed with regard to the innovative performance of the pharmaceutical industry. In particular, average research and development costs for a new drug entity have increased more than an order of magnitude and now exceed $20 million per new drug. Development times and risks have also significantly increased. Most importantly, the annual rate of new drug introductions in the United States has fallen to less than one-third the rate which existed in the early 1960's. In a forthcoming paper we consider various hypotheses for these adverse trends; and, on the basis of international comparative analysis, conclude that increased regulation has been a major factor underlying declining innovational performance in the drug industry (see the authors and Thomas). This is consistent with a number of other studies (see Martin Baily, Sam Peltzman, David Schwartzman).

There are clearly foregone health benefits to the public when beneficial drugs are left undeveloped or are substantially delayed because of *FDA* regulatory controls. William Wardell, a clinical pharmacologist, and Louis Lasanga documented many cases in which new drugs developed abroad (and even many American drugs first introduced abroad) generally took several additional years to gain *FDA* approval for use in the United States. Their findings are consistent with our own analysis of the international diffusion of new drug therapies across four countries (the United States, United Kingdom, France, and Germany). Specifically, we found that a majority of all the new chemical entity drug introductions into the United States over the period 1965–75 had a prior introduction in the United Kingdom, France, or Germany. Moreover, if one considers only the twenty-seven new drugs introduced in this period that were specifically classified by the *FDA* in 1974 as *important therapeutic advances*, fifteen had prior introduction in one of these foreign countries, eight became available here and abroad in the same year, and only four were initially available here first.

Of course, the total benefits of *FDA* regulation may exceed its overall costs. We have been concentrating here on the cost side, and the benefits to the public of avoiding harmful side effects of drugs kept off the market surely exist. However, given the *FDA*'s stated policy of giving absolute priority to considerations of safety and efficacy, and ignoring effects on firm costs and innovation, it is almost inevitable that *marginal* costs will exceed benefits and that *FDA* policy will err on the side of being overly restrictive.

As noted in the introduction, Congress, in the Medical Device Amendments of 1976, has extended the *FDA* premarket regulatory controls over a larger spectrum of medical products. If the *FDA* brings a similar regulatory philosophy to bear on this sector to that which it has exhibited in pharmaceuticals, the costs in terms of foregone innovation are likely to be quite high indeed. This is particularly so because innovation in many medical device fields (such as heart pacemakers) has not been characterized by large economies to scale and several major new products have emanated from small firms. Such firms would be least able to finance or bear the costs and risks of an expensive, lengthy, and uncertain premarket regulatory approval process. Moreover, we have shown elsewhere (1976) the rapid increases in research and development costs that occurred in pharmaceuticals over the post-Amendment period has operated to concentrate innovation in the very largest drug firms. One might expect similar, but perhaps even more dramatic structural changes for many medical devices, if regulation in this area proceeds with a comparable approach to *FDA* regulation of pharmaceuticals.

III. Summary and Conclusion

While it is still too early to evaluate conclusively the recent wave of consumer product safety regulation, the evidence thus far indicates that serious resource misallocation is taking place and is likely to continue. The regulators of product safety tend to rely solely on direct controls (product bans and standards) and to be concerned with the benefits only, as measured in the number of lives saved and accidents avoided. They ignore, often intentionally, the costs of their controls. Unless this "safety imperative" approach to regulation is changed, the problems of resource misallocation will multiply over time as regulatory controls are extended to several additional product classes.

POLICY FORUM

Regulation: Asking the Right Questions

by Peter H. Schuck

Peter H. Schuck, a lawyer, was, until recently, Deputy Assistant Secretary for Planning and Evaluation at the Department of Health, Education and Welfare. Prior to that, he was Director of Consumers Union's Washington office. Currently a visiting scholar at the American Enterprise Institute, he will join the Yale Law School faculty in July.

In recent years, a vast literature on regulation has emerged, a literature to which many professional disciplines have contributed. Historians have chronicled the circumstances under which existing regulatory systems were established. Political scientists have described (often incorrectly) the political and institutional dynamics of regulation. Lawyers have analyzed the legal rules that govern the procedures and substantive policies of regulatory agencies. Economists have measured the economic performance of regulated industries and the costs and benefits associated with regulatory activities. And politicians, whose intellectual effusions fill countless volumes of their professional journal (the *Congressional Record*), have debated the merits of regulation in general and of regulatory proposals in particular.

Very little of this analysis, however, bears upon the question that policy makers most need to answer: How well is a regulatory program likely to be *implemented* in the real world? To be sure, economic theory has analyzed "market failure" (i.e., market conditions, such as external effects, inadequate consumer information, the "free rider" problem, inadequate tort remedy, monopoly, etc., which may justify regulatory intervention on efficiency grounds), and the efficiency and distributional consequences of particular regulatory proposals or programs ("cost-benefit analysis"). But the "market failure" and "cost-benefit" criteria are *minimal* ones, necessary but not sufficient to justify a regulatory intervention. Virtually all markets, after all, are imperfect to some degree, especially consumer markets in which, among other market flaws, the information possessed by consumers is often inadequate. Third party effects (called "externalities") which impose costs of activities upon persons who do not fully benefit from them (or vice versa) are also pervasive in a crowded, interdependent society, particularly one in which equity considerations (e.g., the income distribution and the fate of low-income groups in the marketplace) have increasingly come to affect the preferences of voters-consumers.

But if markets are almost always flawed, so are regulatory interventions by government. However inadequate consumer information may often be, information in the political marketplace (where there is no FTC to police claims) is probably worse. A consumer purchasing a product may know little about its performance, safety, durability, etc., but that pales in comparison to what the Consumer Product Safety Commission (CPSC) does not know but would have to know in order to prescribe a safety standard that would maximize the welfare of millions of consumers while taking into account the dynamic economic and technical realities of hundreds of firms. Much the same is true of externalities. Market transactions in an unsafe product will often harm third parties (e.g., those injured in accidents or compelled to pay higher insurance premiums) without compensation, but the potential for uncompensated, unforeseen harm to consumers, workers, stockholders and other third parties resulting from uninformed economy-wide or industry-wide regulations may be far greater. Other aspects of what might be called "regulatory failure"—for example, protracted, legalistic and expensive proceedings; a chronic tendency to lump differently-situated persons or firms into broad, unrefined regulatory categories; discouragment of long-term investment; discouragement of innovation—must also be weighed against the inevitable imperfections of the market.

Cost-benefit analyses are also invariably flawed. The reasons for this are well-known: the difficulty of identifying and quantifying many costs and benefits; the inevitably arbitrary nature of valuations of human life or health; the special difficulty of evaluating extremely low risk but catastrophic events (e.g., a meltdown of a nuclear reactor); the problem of interpersonal and intergenerational comparisons of utility; and many others. These limitations imply that cost-benefit ratios, whether favorable or unfavorable, should (like analyses of market failure) constitute only the beginning of the inquiry, not its conclusion.

To begin to address questions of regulatory *implementation*, one must first possess a theory not only of how markets work but of how regulation—whether of markets *per se* ("economic" regulation) or of other market-related phenomena, such as pollution, pensions or civil rights ("social" regulation)—works. Such a theory must be grounded not only in a knowledge of economics but in a knowledge of law, of politics, and of history; in short, it must be interdisciplinary in nature. Perhaps for that reason, no such theory yet exists. And given the complexity, diversity, and value-laden nature of the phenomena to be explained, any such theory is not likely to be a rigorous one. Nevertheless, this article suggests some modest hypotheses as a starting point.

Most of the propositions that follow must be qualified by the condition "other things being equal." In the

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regulatory world, of course, this condition is never really met. Nevertheless, such generalizations can help us to identify additional criteria or points of reference that can stimulate policy makers to think critically about the likely effects of regulation in real world situations, and decide what form or forms the regulation ought to take. These criteria will be grouped into five general categories relating to: (1) the structure of the market or other phenomenon to be regulated, (2) the informational needs of the regulator, (3) the objectives of the regulation, (4) the enforceability of the regulation, and (5) the political support for the regulation.

THE STRUCTURE OF WHAT IS TO BE REGULATED

The relevance of the structure of the market or other regulated activity to the probable efficacy of regulation extends well beyond the possibility of market imperfection.

Number of Regulatees. Other things being equal, the more numerous the firms, people or processes that must be regulated, the less likely it is that regulation will be effective. This generalization, while perhaps more true of what Charles Schultze has termed "command-and-control" regulation, tends to be true of "incentives" regulation as well. First, if scarce regulatory resources must be spread over a large number of entities, inspection and monitoring become sporadic, thereby diminishing the credibility of regulatory sanctions. The Occupational Safety and Health Administration (OSHA), for example, purports to regulate some five million workplaces. Although OSHA devotes four-fifths of its staff to enforcement, its inspections during 1976 covered fewer than 2 per cent of the workplaces. A probability of inspection for the average workplace of only once in several decades, coupled with very low fines for violations ($37.49 on average in 1976), means that the regulatory sanction is unlikely to be an important factor in and of itself. While private enforcement of a regulatory standard could supplement agency resources (e.g., the anti-fraud provisions of the Securities Act), private remedies are normally not authorized where the administration of a complex regulatory scheme is delegated to a regulatory agency.

Second, the number of entities may be so great as to make it difficult or impractical for the regulator even to *identify*, much less regulate, them all. The jurisdiction of several federal civil rights laws, for example, extends to all recipients and sub-recipients of "federal financial assistance;" no one has ever compiled a list of them, but it would probably include a half million or more entities. Similarly, the FCC has licensed some 13 million CB operators using about 25 million transmitters; with an enforcement staff of 100, it can only respond to the most extreme violators, such as transmissions involving criminal conduct. Finally, as the number of regulated entities increases, their diversity tends to increase as well, creating difficulties to which we now turn.

Diversity of Regulatees: As an artifact of law, regulation manifests what are perhaps the basic tensions of law: the inescapable conflict between uniformity and diversity, between rule and discretion, between certainty and uncertainty, and between the "rough justice" of broad categories and justice tailored to the equities of individual situations. Regulation almost invariably opts for the former of each of those dualities, for several reasons: limited resources, the importance to economic enterprise of predictability, the danger to effective regulation of delay and stale data, and the sheer enormity of the regulatory task.

The experience of the Federal Power Commission furnishes a dramatic example of this phenomenon. When the FPC undertook regulation of producer rates for natural gas in 1954, it began by determining "just and reasonable" rates for each of the more than 3,000 individual producers. By 1960, the sheer number of backed-up rate proceedings had swamped the Commission, and it was compelled to simplify the process drastically by lumping all producers together into fewer than a dozen "areas." Each producer in a given area was required to sell gas at or below the same "area rate," regardless of the cost and profit profile of the particular producer. Because even area data were difficult and expensive to compile, "area rates" were themselves determined by the Commission on the basis of area or nationwide *averages*, further attenuating the relationship between an area rate and the economic profile of any particular firm. Even area-rate regulation, however, proved too complex—the Southern Louisiana area rate was not affirmed by the Supreme Court until 1974—and the Commission in 1974 issued a single "national rate" applicable to all but the smallest producers. Within six months, this "single" rate had been increased by almost 20 per cent, and had been repeatedly encumbered with regulatory exceptions, exclusions and amendments.

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To an even greater extent than its predecessors, the national rate was an artificial construct, bearing about as much resemblance to the economic profiles of the individual producers as the "average American" does to the diverse society that he or she is said to exemplify. In 1978, Congress enacted a *statutory* rate, but in order to provide flexibility found it necessary to provide for some 17 different rate categories. Many similar examples from the area of "social" regulation (such as FDA's attempts to regulate large numbers of over-the-counter drugs for safety and efficacy) could also be adduced.

Regulators cannot reasonably be faulted for adopting such "rough justice" strategies, given the regulatory tasks Congress sets for them and the meager (relative to such tasks) appropriations Congress votes for them. Nevertheless, its inevitable result is that people or firms in radically dissimilar circumstances are treated as if they were alike, producing competitive distortions and gross inequities. The use of the "base year" concept in price regulation, for example, ensures that some firms will enjoy substantial pricing latitude while others will be severely constrained, depending upon how each firm happened to fare in the base year and how typical that year was for each. Similarly, the notion that the small firm is simply a large firm in miniature ignores the very real differences between them with respect to mode of operations, access to capital, accounting systems and many other aspects of economic activity. Yet most regulatory requirements do not—and, as a practical matter, probably cannot—fully take account of such differences. Indeed, when an agency tries to do so, the administrative problems can be immense: one ERISA provision elicited more than 220,000 individual requests for exemption, some taking more than a year to process.

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Where a regulator has jurisdiction over only one or a relatively small number of firms in an industry—for example, state public service commission regulation of public utilities, FCC regulation of interstate telephone service, or some state hospital cost review commissions—the problem of creating competitive inequities through regulation is reduced somewhat (although not entirely, since regulated firms must compete with unregulated firms in capital and other markets). The problems of acquiring adequate information, political support and other resources, however, will remain formidable ones, as the FCC's chronic difficulty in regulating AT&T demonstrates.

The Dynamism of the Particular Market: Some activities (say, telecommunications) are more subject to rapid technological, economic, or other changes than others (say, the practice of law). In general, regulation is most problematical when it is attempting to employ "command-and-control" techniques to regulate firms, industries or activities that are relatively dynamic.

Any regulatory system will tend to develop a political momentum (or inertia) reflecting the power of those groups that have or acquire vested economic, bureaucratic, ideological or political interests in the maintenance of the regulatory *status quo*. Whether it be the interest of trucking interests (and their unions) in cartelization under the auspices of the ICC, of small refiners in regulation of oil prices, of environmental groups in enforcement of anti-pollution laws, or of the congressional small business committees in the enforcement of the Robinson-Patman Act, these commitments make it quite difficult for a regulatory system to respond to changes in its environment. Thus, when rapid technological transformations or dramatic perturbations in the potential competitive situation occur, they create strong pressures for fundamental adjustments which the regulated firms (and their allies) strongly resist. That resistance may be successful (as with the banking industry's use of regulation to prevent competition across state lines) or unsuccessful (as with airline deregulation, the relaxation of certain FCC controls over specialized telecommunications services, and the demise of "fair trade" laws), depending upon a number of political and economic factors. The banking industry, for example, consists of a large number of firms distributed in every congressional district; it tends to be well-connected politically at the local level; it can play the several bank regulatory agencies off against one another; and it is often protected from competition even within the borders of its own state. But even when regulation does adjust to the new technological and competitive realities, it tends to do so only after considerable delay (or "regulatory lag").

A second reason why regulation, especially the "command-and-control" variety, does not sit easily in the saddle of change has less to do with regulatory politics than with the nature of legal rules. Many, perhaps most, regulatory standards are "input," "design," or "process" standards; they prescribe what one must do (or, in the case of credentialling, be) or how one must go about doing it. Yet the technical reality which they describe changes (or should change) constantly; indeed, the very essence of innovation is to alter the nature or mix of inputs and processes to deliver a product or service to consumers more efficiently. For that reason, a "performance" standard is less subject to this objection. Unfortunately, as discussed below, there are limits on the extent to which performance standards can be, or ought to be, employed. And even a performance standard is often undermined by technological change and advances in learning. Many of the "consensus" standards which OSHA adopted in 1971, for example, were performance standards, yet many of these had been rendered obsolete long before 1971, either because the state of the engineering art permitted equally effective but less costly standards or because the state of knowledge concerning the health and safety effects of certain equipment, processes and substances had changed. Nevertheless, many of these are still on the books due to the laborious and controversial process required to develop new ones.

The Existence of Countervailing Interests: While the economic interests of consumers will sometimes coincide with those of regulated firms, they often will not. The interests of polluters, for example, will usually diverge from those of persons living nearby. In such situations, the ability of regulation to protect affected third parties will depend to a considerable extent upon countervailing interests with a stake in challenging and countering the assumptions, data and policy arguments regulated firms press upon their regulators. In some cases, such adversariness inheres in the regulatory program. Regulation of the collective bargaining process by the National Labor Relations Board, for example, systematically pits well-defined, well-organized economic interests—management and labor—against each other. This is sometimes true under OSHA as well. In some cases, the structure of a regulated industry naturally generates some degree of adversariness. For example, the International Trade Commission presides over a process in which pressures by domestic industries for protection through trade restrictions are sometimes (though not always) countered by importers and manufacturers favoring liberalized trade. In still other cases, environmental, consumer or other "public interest" groups may help fill the void. EPA, the FTC, and the CPSC, among others, have encouraged this approach. Two formidable forces—the regulatory agencies themselves and congressional committees—have (in recent years, at least) often attempted to perform this adversarial function, with varying success. Taken all together, these countervailing interests have helped to subvert the conventional wisdom about the inexorable, irreducible pro-industry bias of regulation, especially (but not exclusively) in the case of "social" regulation.

Even when one of these countervailing forces is operating in a regulatory system, of course, inequalities in information, technical skills, political support and other resources will advantage one interest or another; in the nature of the case, it is difficult to see how it could ever be otherwise. Nevertheless, a regulatory system in which adversariness, through one or another of these mechanisms, is a reality is more likely to generate policies that take into account the wide variety of interests implicated by important regulatory decisions.

THE INFORMATION NEEDS OF REGULATORS

One of the principal justifications for regulation is the market failure that results from inadequate consumer information. Yet regulation does not obviate the need for such information; it simply shifts the locus of that need from the consumer to the regulator, while vastly increasing the quantity, quality, and types of information needed.

The Availability of Information: Regulators ordinarily need a great deal of information in order to make sound regulatory decisions—information concerning costs; benefits; consumer preferences; quality-cost trade-offs; effects of alternative decisions on the environment, employment and competition; and on many other subjects. Almost invariably, much of that information is in the exclusive possession of the regulated industry and some of that (e.g., cost data or trade secrets) may be legally protected against disclosure to the public. Nevertheless, the extent to which regulation-relevant information is already in the public domain or can be obtained through legal process by the regulator does vary. The Equal Employment Opportunity Commission (EEOC), for example, has access to most of the occupational, salary and other such information it needs to construct a *prima facie* case of employment discrimination against a firm, and the CPSC can obtain much data on the incidence and cost of consumer injuries, the engineering of regulated products, and the cost of proposed safety requirements. On the other hand, the FPC (and its successor) was almost wholly dependent upon producers of (and drillers for) natural gas for the basic information upon which its rate formula was based, despite the fact that the industry data were demonstrated to be highly questionable. Access to needed information, of course, does not assure that it will be used either intelligently or fairly, but an agency that cannot even obtain it is almost certain to make poorly-supported decisions.

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Finally, "economic" regulation often undermines the valuable information implicit in costs and prices; this may be intentional (as with Regulation Q, which in effect mandates that small savers subsidize homeowners) or not (as with "regulatory lag" in public utility regulation). On the other hand, much "social" regulation is designed to enhance the availability and value of cost and price information by making such information reflect the full, "true" costs of doing business.

The Quality of Information: The quality of information, of course, is related to its availability to the extent that it is open to challenge by someone other than those who have supplied it. Beyond the question of its availability to the regulator, however, its quality may vary considerably depending upon a number of factors. Data may be "soft" due to the primitive state of scientific knowledge (e.g., the environmental and health effects of certain chemicals at various levels of exposure), or to the irreducibly subjective nature of the phenomenon being regulated (e.g., the relationship between staffing ratios and "quality" day care). It may be suspect by reason of the self-interested character of its source (e.g., the American Gas Association's data on gas reserves); or the incapacity of third parties to evaluate it either as a legal matter (e.g., confidential wage and price data submitted by industry to the Council on Wage and Price Stability) or as a practical matter (e.g., data submitted to USDA under the incredibly complex program of dairy price supports). And it may be stale due to the protracted nature of many regulatory proceedings (e.g., one proposed merger of a major railroad gained final ICC approval only after 12 years, by which time the line was bankrupt).

The quality of regulatory information, moreover, may be affected by the distribution of the benefits and costs of a regulatory proposal. Robert Reich has pointed out that cost-benefit analysis is more likely to be demanded and supplied by both opponents and proponents of a proposed regulation in those instances (e.g., much environmental and safety regulation) in which its costs are highly concentrated and its benefits are widely dispersed, than in those instances in which the reverse is true. Other things being equal, the quality of information available to the regulator as a result of those analyses is likely to be better than in their abse[illegible]

The Quantity of Information: Regulation through economic incentives tends to require far less information on the part of the regulator than regulation through "command-and-control" techniques. Since regulatory information of high quality is often difficult to come by, that is no small virtue. A regulator designing an effluent tax, for example, need not know in detail the technology or the cost profiles of firms; he need only know the benefits that particular reductions in effluent level will generate and then set the tax accordingly. Moreover, if experience suggests that the tax is too high or too low, its level can be adjusted far more easily than can a regulation which mandates certain specified inputs or processes and on which firms have relied through large investments in plant or machinery. A performance standard shares some of these attributes of incentives, but because it does not (as the tax does) give a firm the freedom to pollute at any level it wishes (so long as it is willing to pay the social cost), the regulator cannot rationally set the level of the standard without knowing what the cost of compliance will be to firms. On the other hand, *enforcing* "incentive" regulations may require more information than enforcing input, design or process requirements, a possibility discussed below.

THE NATURE OF THE REGULATORY OBJECTIVE

The particular task that Congress sets for the regulatory agency will not necessarily control its future behavior, for the agency is inevitably transformed over time from an instrument of legislative policy into an institution with an organic life and purposes of its own. Moreover, most regulatory statutes are exceedingly ambiguous (and sometimes even contradictory) in defining the regulatory objectives. Thus, the CPSC must eliminate "unreasonable risks of injury;" the ICC must set "just and reasonable" rates; and civil rights statutes typically proscribe "discrimination" without defining it. And particular regulatory objectives, such as occupational health and safety, are ordinarily mitigated by other regulatory objectives (such as "feasibility") with little or no guidance given as to how these values should be traded off against one another. Nevertheless, an agency's formal objectives are important in establishing a regulatory "mood;" they define the outer boundaries of its principal mission and other institutions, especially the courts, will be called upon to enforce that mission once it begins to stray. Two dimensions are especially important to a regulation's efficacy: the substantive content of its objectives and the direct measurability of their achievement.

The Content of the Objective: Some regulatory objectives are more easily achieved than others. To a great extent, the strengths and limitations of regulatory agencies correspond to the strengths and limitations of law itself. Thus, regulatory agencies, like the law, tend to be better at regulating procedures and the flow of information than at regulating market characteristics (e.g., the price, quality and health and safety effects) which require at the margin a tradeoff of important economic and social values. That is certainly not to deny that regulating such characteristics is often essential in order to protect the public. It is only to say that this kind of regulation tends to be far more difficult—and errors far more costly to society—than regulating information and procedures. To be sure, the distinction between these types of regulatory objectives will not always be clear-cut: The proper functioning of markets depends upon information and procedures, and both are themselves commodities which are often marketed (as the durability of *Consumer Reports* and labor arbitration demonstrate); moreover, the regulation of procedures and information generates costs and often implicates important values and interests. But it remains the case that what the SEC, NLRB, Commodity Futures Trading Commission and Federal Elections Commission (FEC) attempt to do tends to be quite different from—and far more manageable than—what the ICC, OSHA, EEOC and energy regulators attempt to do.

The most important differences relate to what Dahl and Lindblom have called the "problem of calculation" and the "problem of control." The quantity, type and quality of data that the SEC needs to determine what kinds of information investors should have for the efficient functioning of the securities markets; that the NLRB needs to determine what is an appropriate bargaining unit or whether an unfair labor practice has been committed; or that the FEC needs to determine whether a particular activity by a candidate constitutes a campaign "expenditure," are very different from that which the ICC needs to calculate "just and reasonable" rates for competing modes of transportation; OSHA needs to devise health and safety standards that will protect workers while not unduly jeopardizing their jobs; the EEOC needs to determine whether employers are engaging in discrimination or merely reacting to labor market conditions that confront them; or the Department of Energy needs to price and allocate scarce gasoline supplies. The information required for the former tasks, while often imperfect, tends nonetheless to be manageable, available and reasonably stable over time; moreover, it possesses few of the infirmities of information discussed earlier. In contrast, the latter tasks tend to require enormous quantities of informa-

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tion, much of this is obsolete by the time it is ready to be used, much is impossible to come by at any reasonable cost, and that which is available will often be of low quality.

If the problem of calculation is especially formidable with respect to regulation of price, quality and other market characteristics, the problem of control is no less so. Compliance with the SEC's disclosure requirements, the NLRB's procedures, or the FEC's strictures is relatively easy to monitor. Consequently, there is less likelihood of competitive distortions, black markets or other forms of evasion. In the case of "economic" and much "social" regulation, however, non-compliance is more difficult to detect, for several reasons: the economic incentives on the part of buyers and sellers to evade requirements are especially great; what constitutes compliance is far more ambiguous; and there tend to be fewer countervailing interests capable of enforcing compliance. To establish that a firm failed to make certain financial disclosures to the public or failed to follow prescribed procedures is one thing; to establish that it discharged pollutants in excessive quantities, sold a substance that is carcinogenic, discriminated in hiring or engaged in an anti-competitive merger, is quite another. Institutional investors, labor unions or opposition candidates are well positioned to try to police the former; ordinary consumers, workers or small businesses will have little incentive or opportunity to police the latter.

The Ability to Measure Performance: The extent to which regulatory objectives are in fact achieved can be measured more directly with respect to some objectives than others. OSHA, for example, can gauge the extent to which it has improved occupational *safety* far more readily than it can with respect to occupational *health*. Thus, the number and/or severity of industrial accidents per man-year is a reasonable measure of the former, for an "accident" is a relatively well defined phenomenon whose cause is usually (though not always) ascertainable. (Even here, of course, the accident rate clearly is affected by factors other than OSHA, as evidenced by the recent increase in lost work days and serious industrial accidents). Many occupational diseases, however, possess neither of these attributes; their symptoms are generalized, may not even appear for a generation or more and have uncertain causes.

The extent to which performance can be measured directly is often a matter that the regulator cannot control; as the example of occupational disease suggests, it may be inherent in the particular regulatory task. In this case, the regulator will usually be obliged to devise operational substitutes for the regulatory objective, proxies the achievement of which can be measured directly. These proxies generally take the form of "input" requirements (e.g., that only licensed physicians may perform certain tasks), "process" requirements (e.g., that certain procedures be undertaken) or "design" requirements (e.g., that certain types of machinery be used). Even when "outcome" or "performance" requirements are available, they may be impractical because of the administrative difficulties of actually measuring or enforcing them. It is far easier, for example, to enforce affirmative action requirements (at least in the first instance) by counting the proportion of minority employees in a firm than by attempting to evaluate its subjective "good faith" in seeking such employees. Similarly, an OSHA inspector can easily measure the distance between a cutting machine and a guard rail, but measuring the safety performance of such a machine directly would require that the inspector wait until after the damage had been inflicted, thereby defeating the regulatory objective.

In many cases, however, performance or outcome standards or economic incentives are preferable. EPA, for example, is increasingly attempting to regulate the amount of permissible effluent rather than regulating the pollution control technology; similarly, HEW has devised new outcome-oriented performance measures for the Head Start program. Such standards are superior in several respects. First, they prescribe only the desired result, leaving to the informed discretion of the regulatee how best to achieve that result. This division of responsibility recognizes the comparative advantages of both regulator and regulatee, and increases the likelihood that the most efficient solutions will be devised. (On the other hand, the regulatee may select a solution that is efficient but may nevertheless be deemed objectionable. Thus, firms may require workers to wear uncomfortable personal protection devices rather than install more expensive engineering controls). Third, they avoid involving regulators in the minutiae of industrial engineering, management science, applied chemical research and the like, except to the extent necessary to prescribe the desired outcome. Finally, they provide measures against which the performance of both regulator and regulatee can be judged because the measures relate directly to the real purposes of the regulation, rather than to some imperfect proxy. Indeed, regulators and regulatees often resist performance standards for this very reason (although the stated complaint will often be not that performance measures are objectionable *per se*, but that the particular standard chosen is not an appropriate measure of the regulatory objective).

THE ENFORCEABILITY OF REGULATIONS

The disposition of people to obey a legal requirement depends upon many factors (including the costs of compliance, the clarity of its meaning and the extent to which it is perceived to be reasonable or just), but a critical one is the anticipated cost of non-compliance. For this reason, the enforceability of a regulatory scheme is an important determinant of its real-world effectiveness.

There may well be few legal requirements for which some loophole or evasion cannot be devised by a regulatee with both a strong incentive to do so and a creative lawyer to help; even under ordinary circumstances, regulations often cannot be effectively enforced. Nevertheless, some regulations are more readily enforceable than others; enforceability depends upon a number of factors, many of which relate to points made earlier. First, the resources of the regulator will often simply be inadequate to the tasks of identifying non-compliance and mobilizing the administrative apparatus, especially when the regulatees are numerous and not highly visible. Federal day care regulations have long gone unenforced for this reason (among others). It is simply impossible to identify, much less monitor or inspect, the tens of thousands of formal and informal day care arrangements subsidized by federal dollars. Second, a regulation's ambiguity, often desirable for policy or political reasons, may be so great as to preclude enforcement, either as a matter of law (as a federal appeals court recently found with respect to Department of Energy pricing regulations) or as a matter of fairness (as with the federal day care regulations). Third, certain regulations penalize what the price system rewards, thereby realizing the often considerable potential for black markets in the prohibited activity, discrediting the regulation itself and calling into question the fairness of selective enforcement. The regulation of marijuana, the rationing of gasoline and state taxation of cigarettes are examples. Finally, enforcement may not be feasible for political reasons, another way of saying that many people find the prohibited activity profitable or otherwise desirable.

THE POLITICAL SUPPORT FOR REGULATIONS

Regulation is not simply a legal, administrative and technical phenomenon; it is ultimately and inescapably a political one as well. Our decentralized, fragmented political system assures that no important regulatory program can be put in place without the mobilization of significant political resources. Once established, a regulatory agency must find sources of continuing political support in order to retain the integrity of its authorizing legislation, obtain adequate appropriations, pursue its own policy priorities, control the management of its internal affairs and sustain its enforcement efforts. While the apparent immortality of virtually all regulatory agencies attests to their success in developing such support, agencies do vary considerably in the strength and durability of that support. For example, the older agencies primarily concerned with "economic" regulation of particular industries long achieved notable success in conventional political terms, yet some, such as the CAB, FCC and ICC, have seen their autonomy and support erode under the impact of new political forces and coalitions. Others, such as the FTC, SEC and the bank regulatory agencies, have received ever more authority and influence. Even among the newer agencies charged with "social" regulation, political strength is highly variable. EPA and the Food and Drug Administration have demonstrated great ability to resist incursions on their autonomy and authority, while the CPSC and the Office of the Civil Rights have been more vulnerable.

Although there is no simple explanation for these differences, certain generalizations seem plausible enough. It seems clear, for example, that regulation significantly benefitting a well-organized constituency dispersed among all congressional districts while spreading the costs over a large number of people in ways that are not highly visible, will tend to generate substantial political support; regulation that distributes benefits and costs in the opposite way will not. Certainly, the political strength of the agencies engaged in "economic" regulation can be explained in such conventional political terms. (What is more difficult to explain in such terms is the growing strength of their opponents.) Many "social" regulators also derive their support from relatively well organized and widely dispersed interests (such as environmental groups and labor unions) and their allies in Congress, the agencies and the media. Still, it remains intriguingly unclear why, for example, some health and safety regulators, such as FDA, EPA and the National Highway Traffic Safety Administration, manage to sustain public support for their activities while others, such as the CPSC, do not. Such differences may reflect factors such as the political skills of the agency's leadership which cannot be systematically analyzed. Whatever their cause, however, these differences are highly relevant to the ability of each agency to achieve the regulatory tasks that are set for them or that they set for themselves.

> Our political system has come to be dominated by two views: that a public policy is to be justified less by its consequences than by the motivation animating its proponents, and that concerns about implementation in the *real* world of regulations spawned by the *political-bureaucratic* world are niggling details that can safely be deferred until after the regulations have been signed.

CONCLUSION

The criteria that have been discussed do not exhaust those that are relevant to deciding whether, or to what extent, or in what form, to regulate. Certainly, there is nothing arcane or particularly technical about them; indeed, once one reflects upon them, they appear quite obvious. Yet with a few exceptions, such criteria are rarely discussed in public debates concerning regulation. Indeed, even the current mood of skepticism concerning regulation, as manifested in the Administration's regulatory reform proposals, has failed to accord much significance to these questions, preferring instead to focus upon the more systematic use of cost-benefit analysis (a matter which, as discussed above, should be regarded only as a threshold inquiry, only rarely decisive).

It is important that we attempt to understand why this should be so. One answer—that it is in the interest of powerful political forces that these questions not be seriously addressed—begs the most important questions and is, in any event, almost tautological. A more useful explanation may be that our political system has come to be dominated by two views: that a public policy is to be justified less by its consequences than by the motivation animating its proponents, and that concerns about implementation in the *real* world of regulations spawned by the *political-bureaucratic* world are niggling details that can safely be deferred until after the regulations have been signed. If this explanation is correct, then the remedy can come, if at all, only through a change in public views as refracted by the political process. Questions, after all, are not likely to be asked unless people truly desire the answers. ■

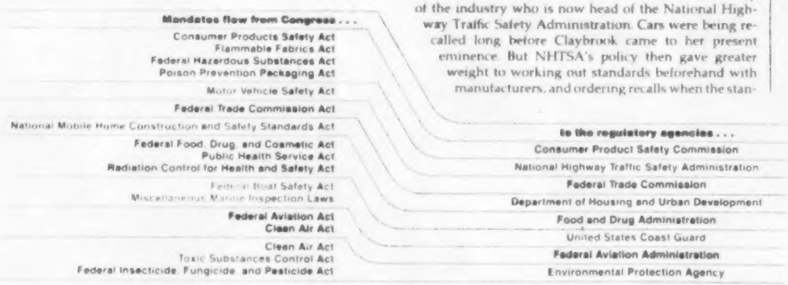
The Mindless Pursuit

Out of this nettle, danger, we pluck this flower, safety.
—Henry IV, Part I

Now ascending among the many blessings that the citizenry expects of government in our society is that flower, safety. Popular demand for this latest entitlement has become practically a national frenzy, and the rush is on to give us full protection from those former-friends-turned-enemies, the myriad products and conveniences and adornments of the industrial age. The presumption is that safety can be wrung in ever-larger increments from manufacturers, who are thought to be exposing us all to needless hazards in return for the equally needless addition of a few pennies of profit. Only make them forgo this petty gain, only force them to build more safety into new products and to fix what they have already put out there on the market, and there you have it—behold the bargain-rate splendors of the riskless world.

Right now, we are pursuing this chimera in two different but related ways, both of which can safely be called dangerous. Carrying out with religious zealotry the sweeping mandates of Congress, regulatory agencies engaged in social governance are forcing the recall of millions of products in the name of consumer protection. And instead of supplying sanity, the courts are regularly interpreting the law to hold manufacturers liable for huge sums when their products can in some way be blamed for injuries. Both agencies and courts frequently ignore or misrepresent true cost and evade the question of who is going to pay it; both accept the appearance of social benefit in place of its reality; and both bring about an uneconomic allocation of risk, shifting too much away from the consumer and back upon the manufacturer. Cost/benefit ratios are admittedly complicated in this field, especially when they concern, as they sometimes must, suffering or death. But it remains inexcusable for our society to be so deceived by the desire for yet another gift by government that we refuse to consider how today's policies will run up tomorrow's bills. Relatively speaking, Faust was a long-range planner.

The primary enforcement tool being used to bring us more safety is the product recall, and the most convincing display of its power can be seen in the confrontation between the government and the auto industry. The protagonist there is Joan Claybrook, the intelligent, formidable, Nader-trained, bred-in-the-bones adversary of the industry who is now head of the National Highway Traffic Safety Administration. Cars were being recalled long before Claybrook came to her present eminence. But NHTSA's policy then gave greater weight to working out standards beforehand with manufacturers, and ordering recalls when the stan-



Mandates flow from Congress . . .
Consumer Products Safety Act
Flammable Fabrics Act
Federal Hazardous Substances Act
Poison Prevention Packaging Act
Motor Vehicle Safety Act
Federal Trade Commission Act
National Mobile Home Construction and Safety Standards Act
Federal Food, Drug, and Cosmetic Act
Public Health Service Act
Radiation Control for Health and Safety Act
Federal Boat Safety Act
Miscellaneous Marine Inspection Laws
Federal Aviation Act
Clean Air Act
Clean Air Act
Toxic Substances Control Act
Federal Insecticide, Fungicide, and Pesticide Act
to the regulatory agencies . . .
Consumer Product Safety Commission
National Highway Traffic Safety Administration
Federal Trade Commission
Department of Housing and Urban Development
Food and Drug Administration
United States Coast Guard
Federal Aviation Administration
Environmental Protection Agency

That list of federal laws above may seem long, but it is by no means complete; lots of states, in one way or another, have the right to order the recall of consumer products. This outpouring of legislation has led to countless recalls, including those listed at the far right. It may seem odd that the Department of Housing and Urban Development was concerned with the recall of 2,000 Tappan stoves thought to have gas leaks. HUD has jurisdiction over the mobile homes in which the stoves were installed. The Consumer Product Safety Commission has recently been giving "consumer products" a broad definition. It thinks that amusement park rides are a consumer product, an argument now challenged in court by Walt Disney World Co. But the CPSC did work out a consent agreement with Chance Manufacturing Co. under which Chance fixed the restraint system on some cars it makes for amusement parks. The FAA, in a single stroke, recalled the nation's entire fleet of wide-bodied aircraft. It ordered extensive structural changes in all 335 of those planes after a door on one plane blew out, and the sudden decompression buckled the floor.

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# of Safety

by WALTER GUZZARDI JR

dards were not met; although the manufacturers groaned about the standards, at least they knew what they had to do. But today, while NHTSA is still writing standards, the agency seems to have lost its interest in them as a means of effecting recalls. "NHTSA's standards have to be so minimal that they would be self-defeating," says Lynn Bradford, director of the office of defects investigation. Besides, NHTSA took one of its few beatings in court after trying to impose complicated standards for air brakes on trucks.

So NHTSA has been moving its legal base to higher ground. **It is now making extensive use of its power to order recalls whenever *substantial numbers* of a *safety-related defect*** show up, and present an *unreasonable risk* of accident or injury. From those wide-branching concepts, which derive from the Congress, the bodies of the auto companies as we know them today may presently swing. For by its rulings and the generous interpretations of the courts, NHTSA has made those italicized words mean almost anything it has wanted them to mean. Any number can be substantial; any failure of any part even after years of good performance can be a defect; any defect may be safety-related, and any defect related to safety can present an unreasonable risk—not literally, but very nearly, that is the legal case today. As one embittered official at Ford Motor says, "There are no standards. Whatever we do, NHTSA and the courts just say we should have done it better."

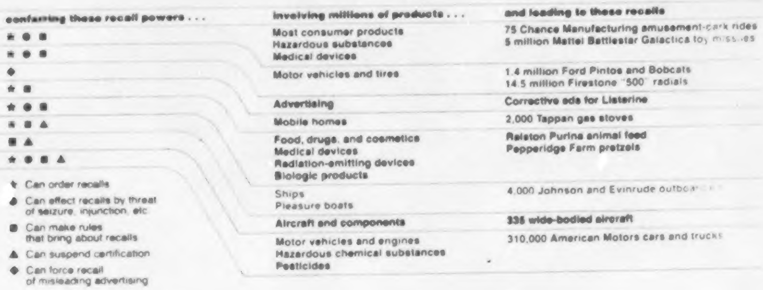
For a while, Ford and General Motors fought to keep from ensnarement in that particular web. But the courts, which like Congress have felt the heat of the consumer movement, have found NHTSA to be very, very right. For instance:

■ **A stop at the Pitman Arms.** "Pitman arms," part of the steering mechanisms, were failing in some 1959-60 Cadillacs when NHTSA began its investigation in 1974. The failure was coming only with very sharp turns made at very slow speeds—most often when a car was being parked. Since no one could prove injuries as a result of the failures, and since the 43,400 cars of that model still left on the road had gone through 96 percent of their lives, G.M. could not see the "unreasonable risk." But the court held that whenever steering or other vital components fail without warning, that's an unreasonable risk. In the end, G.M. had to notify the owners of the remaining cars (by then eighteen years old) that they had a defect. G.M. made the repairs without charge.

■ **Breaking point.** Seat pins were breaking off one side of the driver's seat in some 1968-69 Mustangs and Cougars. NHTSA cited a failure in fifty-seven out of some 500,000 cars. Ford pointed out that the defect had never led to a serious injury. The company lost, and recalled the cars.

■ **Reinventing the wheel.** A number of wheels on some 1960-65 G.M. trucks were collapsing when the load limits of the trucks were exceeded by overweight campers. G.M. argued that the overloading, against which it warned in its instruction manuals, constituted owner abuse. The court held that there was abuse, all right, but it was "reasonably foreseeable"; everybody knows trucks are going to be overloaded. Only "unforeseeable abuse" might have excused G.M.

Supporting a G.M. petition to the Supreme Court, Volks-



conferring these recall powers . . .	involving millions of products . . .	and leading to these recalls
★ ● ■	Most consumer products Hazardous substances Medical devices	75 Chance Manufacturing amusement-park rides 5 million Mattel Battlestar Galactica toy missiles
★ ● ■	Motor vehicles and tires	1.4 million Ford Pintos and Bobcats 14.5 million Firestone "500" radials
◆	Advertising	Corrective ads for Listerine
★ ■	Mobile homes	2,000 Tappan gas stoves
★ ● ■	Food, drugs, and cosmetics Medical devices Radiation-emitting devices Biologic products	Ralston Purina animal feed Pepperidge Farm pretzels
★ ■ ▲	Ships Pleasure boats	4,000 Johnson and Evinrude outboa
■ ▲	Aircraft and components	335 wide-bodied aircraft
★ ● ■ ▲	Motor vehicles and engines Hazardous chemical substances Pesticides	310,000 American Motors cars and trucks

★ Can order recalls
● Can effect recalls by threat of seizure, injunction, etc.
■ Can make rules that bring about recalls
▲ Can suspend certification
◆ Can force recall of misleading advertising

"Human factors" are responsible for most automobile accidents in America.

wagenwerk AG made the point that "nearly every accident situation involving an automobile, no matter how bizarre, is foreseeable, if only because in the last fifty years drivers have discovered just about every conceivable way of wrecking an automobile." But the Supreme Court declined to hear the case. Since then, the auto industry has been reluctant to fight NHTSA in the federal courts.

Recalls also dump truckloads of unfavorable publicity on the car companies because of the tone of the letters that the companies have to send out to begin the recall. Millions of copies of the letter may go to owners of the cars being recalled, even when only a small percentage of the cars have that particular defect. The letters, which are practically dictated by NHTSA, recount the horrors that *might* happen: a typical one might say that the owner's car may have this defect, that if it does the part might fail, and if that happens the driver may lose control of the car and there may be an accident. All that is true. But it is also a doomsday scenario.

Just what would happen if the angry Claybrook became angrier still nobody knows, but the scene might do for a movie by Irwin Allen, the master of disaster. In 1975, about 1.5 million vehicles were recalled. In 1976, still pre-Claybrook, the number went to three million. In 1977, however, a record number of 10.7 million vehicles were recalled; that number included about as many cars as were manufactured that year. Last year recalls came down to 7.9 million. But if that made the year a numerical disappointment for NHTSA, there were compensations: victories were won over Firestone (14.5 million tires recalled) and over Ford with the Pinto recall.

As for 1979, it could be a wonderful year for NHTSA. The agency has issued two "consumer advisories," and has got out other kinds of publicity as well, warning that transmissions in some Ford vehicles have been jumping from park into reverse; included in the advisories are allegations that twenty-three deaths occurred as a result. (NHTSA's advice to drivers includes the suggestion that they turn off their engines when they get out of their cars, which would certainly be a cheap fix.) Ford has done enormous amounts of testing, but says it has found no evidence of any defect; it thinks that the information coming in about the number of accidents has been skewed by NHTSA's publicity. But the shadow of a recall, amounting to nine million cars and trucks made from 1970 to 1978, still hangs over Dearborn. Whether NHTSA would ever recognize any limits to recalling is anybody's guess. Frank Berndt, associate administrator for enforcement, muses that "if we were faced with a massive recall, say 15 million cars, we might try something else, rather than destroy the industry."

The crucial questions about all those recalls, of course, are how much they cost, and how much safety they are buying. None of the car companies breaks out figures about recall costs, which consist of payments at retail labor rates to the dealers who do the work, and the cost of the replacement parts plus some profit to the dealers for handling them. Neither will any of them estimate the value of the executive time spent on recalls —Henry Ford II himself worked hard on the Pinto case—or the public-relations damage. Still, there's not much doubt that the auto companies have had to lay out hundreds of millions of dollars for recalls, and that amount is being repaid by new-car buyers. When it passed the law obliging manufacturers to pay for recalls, the Senate Commerce Committee thought it was ensuring that "the consumer never again will be forced to pay for the repair of safety related defects," but its rhetoric was better than its economics. Chester V. Barion, general manager of the parts and service division at Ford, remarks, "These recall costs are substantial, and they will be reflected in future pricing." To whatever the total cost is to the industry must be added, of course, the social cost of operating NHTSA: it has spent $1 billion in its twelve-year life.

As for safety, a very strong inference can be drawn that society could be getting much more of it by spending the money in a different way. Lots of research goes to show that unsafe vehicles cause a very small proportion of highway accidents and deaths. The definitive study on accident causation by a special research group at Indiana University found that some 75 percent of auto accidents are caused by "human factors," generally meaning speeding, inattention on the part of the driver, and bad decision-making in a crisis

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Research associate: Stratford P. Sherman

The warnings put on toxic household products simply can't protect everybody.

—all worsened by drinking. "Environmental factors," such as icy roads, obstructed view, and poor highway design are the next most frequent cause. "Vehicle factors" cause only about 5 percent of accidents. Brake failures and bald or underinflated tires take a big chunk of that percentage.

So instead of pressing on with recalls, it would be more rewarding to urge better driver education, regular vehicle inspection, and tougher laws about drinking. But those are unpopular causes to promote. NHTSA has found it politically much more rewarding to wheel up the cannons and open fire on those centers of power around Detroit.

The terrain there is also pocked with shells fired by another body, the Environmental Protection Agency, which has the power to order recalls of cars that do not meet emission standards. Since the advent of the Carter Administration, the EPA, like NHTSA, has been shooting from the high ground. The shift in emphasis has come with the methods of testing for emissions, which have moved from inspection and certification of new cars in the plants to what is called "end-use enforcement"—testing cars chosen at random from models suspected of being in violation after they have been driven for a while by their owners. EPA says this is the way to find out what is happening in the real world. But a Ford executive points out, "In new-car testing, the average is what governs. Now EPA is looking not at averages but at individual cars. We're petrified."

What worries Detroit most is that this shift may oblige the companies to pay for fixes on cars whose antipollution devices have been abused or tampered with by their owners. There's some reason for this fear, because while pollution controls can upgrade the quality of the air, they can also downgrade the performance of the car. Lots of owners make adjustments to get smoother rides and better mileage—and don't worry much if they increase emissions.

Consequently, there's a big battle coming between the industry and EPA over what constitutes proper maintenance, with Chrysler as the point company. EPA wants Chrysler to recall 208,000 of its 1975 cars that the agency insists are exceeding emission standards. Chrysler says the owners have tampered with the carburetion. EPA replies that the fault lies with Chrysler's carburetor designs and adjustment procedures. Millions of dollars in fixing costs for all the auto companies hang on the case, now before the courts.

Although EPA's new policies toward emissions may greatly increase the costs to the industry and the number of recalled cars, the agency is far from satisfied. Ben Jackson, a deputy assistant administrator at EPA, says, "We could go on ordering recalls and logging numbers and looking good. But it's fool's play to make a numbers game out of this. We want the standards met." Jackson claims that after the manufacturers have been advised that some of their cars aren't qualifying, they present plans for the cheapest possible fixes—"a tweak of the carburetion mixture when a carburetor replacement might be best." Negotiations over what constitutes a proper fix can go on for months, Jackson says, while the companies benefit from the delay: the more time that goes by, the fewer the cars they have to adjust. To end this Ping-Pong game, Jackson wants the EPA to be given more punitive powers, so that the costs of the dilatory tactics to the companies would become too high. Ford denies using such tactics, and shudders at the prospect of still higher costs for emissions control.

By way of its authority over marketing practices, including advertising and warranties, the Federal Trade Commission is also prancing around on the recall stage. Its most interesting role so far began in 1976, when Ford discovered that some of its small cars had pistons that were scuffing cylinder walls. Although the warranties on some of the cars had expired, Ford was making what it calls "goodwill adjustments"—repairs free to those customers who complained. The FTC took the view that the repairs should be offered to all customers, not just complaining ones: what Ford called "goodwill adjustments" the agency looked on as "secret warranties." Ford notified about two million customers that it would make a free fix.

The FTC, though, had got the wind up, and it has gone on to develop a very expansive case against Ford, going far beyond piston scuffing. The commission is charging that Ford is offering "seriously defective cars" for sale, and is misrepresenting them in its advertising as "durable and reliable." In a proposal lunatic even in the religion of regulation, the FTC is suggesting that to protect itself from charges of false advertising, Ford must conspicuously

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"The most dangerous component is the consumer, and there's no way to recall him."

display in every showroom a poster enumerating the twenty principal flaws, both potential and known, to be found in its cars, and must also plaster a defect notice to the windshields of new cars that are "subject to a substantial defect."

Swallowing hard, Ford has responded by saying that its cars are indeed reliable and durable, that it can't find out about defects (which the FTC can't define anyway) until they show up, and besides, in effect, the FTC should drop dead—the case is way beyond its purview. Ford has not got around to suggesting that the FTC should post in its corridors a list of the agency's twenty greatest failings, including its recent questionnaire about practices in the legal profession that the American Bar Association calls "unreasonable, of questionable legality and doubtful usefulness." Still, if the FTC has its way, the auto industry may end up with yet another overseer with de facto power to effect recalls—assuming, that is, that when NHTSA and the EPA get through, there are still some cars left out there.

The FTC has also just worked out with Fedders a consent agreement for the repair of some 40,000 heat pumps. There, the commission contended that selling a product is an implicit assertion that the product is free of defects. That broad theory could serve as the basis for many other FTC-influenced recalls in lots of other industries. Formerly, the FTC confined its recall actions to making manufacturers eat their words. The most famous example involved Warner-Lambert, which was forced to include in its next $10 million of advertising an assertion that "Listerine will not help prevent colds or sore throats."

For all of the deficiencies of those belligerent agencies, they do have generally understandable recall policies, if costly ones, and they never have to wonder what to do. But the Consumer Product Safety Commission, which has played a role in over 1,200 recalls of millions of products during its six-year life, lacks both surety and a proper occupation. The fault lies not with the people but with the purpose. The Consumer Product Safety Act, and the four other acts that Congress has charged the commission with carrying out, add up to the loosest and most indistinct mandate ever conferred on a regulatory body. Without too much exaggeration, the mandate might be summed up as a collective command to make almost everything safer.

Despite the commission's Herculean efforts, there is no way to accomplish that task by regulatory authority. Here and there, the commission may keep or get a perniciously shoddy product off the market. But basically, the CPSC, like NHTSA, has a fatal defect. Its primary thrust has to be directed against product defects and design. But the overwhelming number of product-connected injuries probably come not from faulty products, but from errors or recklessness of the consumer. As E. Patrick McGuire of the Conference Board puts it, "The most dangerous component is the consumer, and there's no way to recall him." By government standards, the CPSC may be a modest spender, but it will cost about $40 million this year, and it requires lots of paperwork from many different companies. On balance, the CPSC just doesn't pass the cost/benefit test.

The troubles and issues go deeper and are far more important at the Food and Drug Administration, but they do not for the most part center on arguments over recall power. The FDA technically has such power only in its oversight over medical devices, such as pacemakers, and over products that emit radiation, such as TV sets and microwave ovens. It has had some disputes over standards with companies like General Electric, Zenith Radio, and RCA in those fields. Besides, while medical devices are usually simple to track down, they can be hard to fix: it's not easy to put a screwdriver to an implanted pacemaker. TV sets, on the other hand, can be fixed readily enough, but they are hard to track after they have been sold to the consumer. Generally, though, industry and agency manage to coexist without too much acerbity and waste in this field.

With food, the FDA has the authority to ban or seize what it regards as a menace to health. It cannot order recalls, but the threat of those other measures is usually enough to motivate a company to run its own recall. Although the FDA sometimes leans too hard on publicity as a weapon against food producers, it manages pretty well in the traditional fields, getting adulterated tuna, lye-sprinkled pretzels, poisonous mushrooms, and botulin-infested soup off the shelves about as well as possible, given the long chain of distribution. The more profound difficulties come with the waves of scientific and technological change that have brought food additives, such as nitrites, and products like saccharin. That area is now swirling with conflict and confusion.

The danger is that the FDA, always being carped at for inaction by some pressure group, will end by opting for safety over all other considerations. It may be moving that way with cosmetics, where it wants authority to certify ingredients as safe before they get to market. The FDA for many

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years has had that kind of authority over ethical drugs, keeping them off the market until they are certified "safe and efficacious", the results range from dubious to bad. In a study that stands as a landmark in the field, Sam Peltzman of the University of Chicago has shown that the proof-of-efficacy requirement has kept some useless drugs from going on sale. But it has also deprived us of lots of beneficial new drugs, and has kept the prices of existing drugs higher by shielding them from competition. On balance, Peltzman computed a huge net loss.

The growth of the recall phenomenon in the past decade has roughly coincided with an explosion in the number of lawsuits brought against companies, large and small, for injuries associated with the use of their products. The two developments have the same provenance: the sense of rising entitlements, and the efforts of the courts and the Congress to institutionalize it.

In the field of product liability, the change comes close to a doctrinal revolution. Until a few years ago, anyone claiming damages for a product-related injury usually had to prove that the product was defective, in the sense that it failed to meet the manufacturer's own standards. One important case held the Coca Cola Bottling Co. of Fresno liable when a waitress was injured by a bottle of Coke that exploded when she was putting it into a refrigerator. She did not have to prove that there had been negligence somewhere in the long skein of Coke production. Obviously, the company didn't intend its bottles to explode; it was liable when they did.

Now that sensible doctrine is being taken to extremes, and strict liability, like Calvinism, holds the maker responsible for everything. We may be coming to the point where all the fault lies with the product, none with the conduct of its owner. Lawsuits have been entertained claiming that cars are defective (that is, not "crashworthy") when they are demolished by railroad trains, and that a car is unsafe when it hits a pedestrian. If football players sustain head injuries, the maker of helmets didn't design in enough shock resistance. The manufacturer has not yet been held liable when some swinger mashes his thumb with a hammer, but that day may come. And the link of causation has been weakened, too: courts have expanded liability to include defects that enhance or aggravate the injury, rather than directly cause it. And some awards have surpassed even the hopes of the plaintiffs, running up beyond all reason.

Recalls have fed this liability monster in several ways. "The number of recalls has surely disabused the public of the notion that we make perfect cars," dryly remarks one company lawyer. "Twenty years ago, people thought Detroit made a pretty good automobile. Now people—and jurors—are saying, 'Can't you do anything right?' " Corporate lawyers also say that after a big recall, the number of private lawsuits increases. And one of them adds, "We often notice that the legal complaints paraphrase the recall letter" —the doomsday scenario.

Some consumers have been shocked to learn that water and electricity don't mix.

Government actions and private litigation also have a way of feeding on each other. When the government starts an investigation, the target company has to produce piles of documents, which later can provide the basis for private suits. The reverse is also true: government agencies monitor civil litigation looking for clues. Warnings issued by regulatory bodies also stir up suits: "Say the FDA starts to talk about side effects from a drug that has been on the market for twenty years," says Michael Hoenig, a lawyer with Herzfeld & Rubin in New York and an authority on products liability. "Shortly thereafter, you might see 200 women claiming to suffer from that complaint." Violations of FDA or CPSC or NHTSA standards can lead to private charges of negligence against a company, but the knife doesn't cut the other way: compliance doesn't immunize a company from strict liability.

In a broad sense, the process at work here is serving a moral imperative. Judges and juries are setting out not to right wrongs, but to compensate the injured. As Reynold M. Sachs, a professor of economics at American University, has explained, the emphasis is not on who is responsible but on who is best able to pay—on who, in other words, has the "deep pocket." So the laws of liabil-

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ity may be turning into a subterranean means for redistributing wealth.

As the trends toward more recalls and more liability go on, manufacturers will indeed make safer products. They will do more testing in their plants and, since absolute safety will remain unattainable, they will take out plenty of liability insurance. But intramural procedures can never be as efficient as the tests of actual use that the consumer carries out, and the premiums for liability insurance have gone up rapidly with the size of the awards being made for damages. So the total costs for putting so much of the incentive for safety on the manufacturer will be very high.

All this will have social effects that Congress, the agencies, and the courts should do well to ponder. To begin with, prices of products will go up to cover these new, forever-escalating components of cost—the added charges for safety. Every consumer, whether he wants or needs the new layer of protection, is going to have to pay the charge; as Reynold Sachs says, "It's a tie-in sale." What is made safe for the village idiot will cost the man of common sense more. Many people would choose to be careful, or to buy their insurance in some other form. Nonsmokers don't want to pay extra for fireproof bedsheets; people who fasten seat belts don't need the costly air bag. But everybody will have to buy such refinements anyway.

Like so many other losses of freedom, this loss will hurt more people than it helps. The beneficiaries will be those who are reckless, for we shall all be guaranteeing them compensation for the injuries they sustain, the cost of which they ought to bear themselves. Further, their ranks may increase as the penalty for recklessness diminishes. To the well off, the cost of subsidizing the reckless won't matter very much; the rich are liable to buy the most expensive products anyway. Most disadvantaged will be the poor, who will find less on the market that they can afford. The low-income man who knows how to handle a chain saw or maintain a truck or take his own fire precautions in a cheap house may find those items beyond his means when they are inseparable from fancy and costly safety devices.

The power mower is not intended to be used as a multipurpose garden tool.

Drawings by [illegible]

In order to be both free and efficient, it seems better to strive for policies that distribute incentives to avoid accidents more sensibly between consumer and manufacturer. Sometimes manufacturers make sleazy and dangerous products, and the consumer feels powerless to change that. But the corrective action transferring more incentive to the manufacturer to make products safe is now going too far.

Buyers and sellers should share more equitably the total costs of accidents—the costs to the consumer of property damage, medical expenses, and forgone income, and the costs to the manufacturer of making a safer product. One way of doing this, which follows a rule by Learned Hand, starts with the assumption that the cost of an accident is $100,000 and the chance that it will happen is one in a hundred. The expected accident cost is thus $1,000. If the manufacturer could have avoided that accident by an expenditure of, say, $300, he ought to have done so, and should be held liable. If it would have cost him $2,000, it would be uneconomic for him to bear the whole burden; the consumer must share it by taking some risk. Such equations can get complicated and tenuous, but they can help point the way to efficiency.

That kind of analysis is often attacked on the ground that, if pushed far enough, it requires that we assign a value to human life, which is too heartless for a humanitarian society. On one level, that is true: life is priceless, death is final. But all that is beyond the reach of law and government. On a different level, we have to affix a value to life, and we do, all the time: for an additional given number of millions of dollars we could build every bridge, or mine every ton of coal, without losing a life, and we could make every railroad crossing accident-proof. But, in a difficult balance, we have decided that we cannot afford those things. Some of that same contour of thought should enter now as the government strives, from our present nettle of danger, to bring us that flower, safety. ■

VIEWPOINT

Crying Wolf

Joan Claybrook

FOR OVER A YEAR, I have observed the rising corporate assault on government regulation, particularly regulation designed to spur business to advance health and safety. In widely circulated advertisements, in letters to shareholders, in pamphlets, speeches, testimony and trade association materials, the federal government is accused of creating unnecessary regulations that cause inflation, retard innovation, destroy jobs, and divert capital investment from "productive" pursuits. Readers will have noticed these corporate attacks on "Big Government," "Bureaucratic Bungling," "Overregulation" and, of course, "The Undermining of the Free Enterprise System." But they will not have noticed much in the way of a response from the regulators. In my opinion, it is our duty as public servants to speak up—because these charges can generate unwarranted loss of respect for legitimate government action. They can demoralize those who are trying to improve conditions within industries, and they can undermine efforts to develop the technological basis for life-preserving progress for workers, consumers, and the environment.

Here is the current corporate view as it appears to me.

- If inflation rages, Washington is the cause and only Washington can provide the cure.
- If there is unemployment, Washington is its taproot and the obstacle to its reduction.
- If there is disease-producing pollution, it is a necessary by-product of a technological society, and Washington's pressure to curb it interferes with "progress."
- If there is serious job-related disease and injury, laws that require investment to prevent such damage to society are not "productive"—as though improving the health of a nation does not add to its wealth.
- If filth, adulterants, and harmful additives are found in meat and poultry products, the solution is not to clean up the industry but to campaign against the Department of Agriculture and the Food and Drug Administration.
- If a company or industry is not doing well, it is Washington's fault for not providing additional "incentives," such as tax preferences or U.S. Treasury checks.

Corporations, in short, are engaged in a massive drive to blame the federal government for what really is the fault of business. At last reading, after all, the American economy was still overwhelmingly in corporate hands—from the land that produces the minerals, foods, and fibers, to the factories that manufacture the goods, to the office buildings that house the capital and managerial resources. Not only is that true but also the corporate economy plays a strong role in deciding how public revenues and resources are to be used. Yes, business regulates government quite frequently, and when it does, curiously enough, it seeks certain kinds of "Big Government" goodies. In short, Uncle Sam is fine when he plays Uncle Sugar. How many trucking or airline companies have been ready to shoulder the old-fashioned rigors of market pricing and entry by supporting proposals to put the regulators of these industries out of business? It is compellingly clear that many corporations welcome government when it is subsidizer of last resort, lender of last resort, guarantor of last resort, insurer of last resort, and cartel-defender of last resort. But when Uncle Sugar becomes Uncle Sam, people-protector of last resort, the corporate tiger bares his teeth and snarls.

In regulating for health and safety, government assumes what I believe to be one of its most basic functions, promoting the general welfare. Too many companies or industries refuse to recognize both the multiple hazards of their technology and the government's legitimate interest in the public's health and safety—despite extensive pesticide and other chemical plant tragedies, food-borne diseases, con-

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taminated drinking water, and the overall degradation of our environment.

Now, the auto industry is not one of those that still opposes the *principle* of government safety regulation. For example, John Riccardo, Chrysler Corporation's chairman, declared recently that "the need for reasonable regulation of the automobile, in the areas of safety, clean air, and energy conservation, is well established and deserves our full support." Henry Ford II was even more charitable, in retrospect, saying on "Meet the Press" (in 1977): "We wouldn't have had the kinds of safety built into automobiles that we have had unless there had been a Federal law. We wouldn't have had the fuel economy and the emission control unless there had been a Federal law."

These remarks point the way to understanding the domestic auto industry's relationship to federal regulation. The industry fights proposed regulations that it later candidly or grudgingly approves. The Big Three auto companies fought California's and later Washington's modest air pollution control efforts. They still fight auto safety legislation such as the proposed requirement for passive restraint systems, and they resist major vehicle recalls. The point is clear: their credibility is not high. It is not merely the way things turned out that reflects adversely on their credibility, but also the way some of the foreign auto companies have shown up the Big Three. The story of Honda and its stratified charge engine (imported into Japan from the United States and refined) is an example. So is the story of Volvo (ranking twenty-seventh in passenger car sales in the United States)—first with shoulder harnesses, among the first developmentally with air bags and crash safety, and now selling the least polluting vehicle on California's Air Resources Board list (Saab is number two).

Given this background and the fact that business is booming for the domestic auto companies, it is dismaying to hear once again that government is undermining the free enterprise system. It is particularly dismaying that, in the last year, some of the industry's top officials have charged government regulations with impeding growth, stifling innovation, putting workers on the streets, and hampering the industry's ability to compete internationally. If, under these regulations, foreign companies can compete here, why is it our companies cannot?

In January 1978, Chrysler's John Riccardo called air bags a product of "overregulation" that will cost $250 to $300 per car, and claimed the overall result of federal regulation would be a $1,000 per car "rip-off" to consumers in the middle of the next decade. In March 1978, Lee Iacocca, then president of Ford Motor Company, spoke of the "threat" of regulation that was "seriously retarding scientific progress, contributing to inflation, damaging competition, costing American workers their jobs and crippling American business in the world marketplace." Thomas Murphy, chairman of General Motors, in a letter to President Carter, has declared that in the early 1980s the average retail price of a car could increase by more than $800 because of federal regulations—something he thinks inflationary as well as likely to produce widespread buyer resistance.

Of course, most industry comments ignore the benefits of regulations, even when they do not inflate the costs—a practice analogous to a corporate annual report's giving full details on expenses but ignoring revenues. So, in 1975 and again in 1977, in attempting to quantify safety benefits, the National Highway Traffic Safety Administration (NHTSA) carried out studies on the societal costs of motor vehicle accidents, costs such as income foregone, medical care, insurance administration, legal expenses. These costs were estimated at $38 billion annually for 1975 and $43 billion for 1977, the rise coming largely in insurance (up 44 percent in the two years) and hospital and medical costs (up over 20 percent). The figures include only the more readily quantifiable economic losses and do not fully measure the tragedy of death and injury, the disruption of family life, the trauma of witnessing a child's pain, or the mental stress of caring for once active and productive members of society now confined to wheel chairs. But if our regulations do reduce accidents, there are measurable benefits aplenty from them, even without trying to quantify the unquantifiable. Moreover, a supporting index for the necessity of automobile safety regulation may be found in the number of vehicles recalled for safety-related defects. Since 1966, about 5 million vehicles have been recalled each year for correction of defects that pose safety hazards. The fact that the procession of recalled vehicles continues unabated indicates a certain laxity of quality control on the industry's part. It is a certainty that, in the absence of the highly visible federal regulatory presence, a majority of the 65 million vehicles recalled since 1966 would be on the road with their defects unremedied.

In the area of fuel economy, the need for regulation is likewise evident. The oil shortage of 1973-74 taught us what could happen if this country continued to rely heavily on foreign sources for oil. Motor vehicles account for about 40 percent of the nation's petroleum consumption. Conservation there is an absolute necessity, given that alternative means of transportation for most individuals are still far in the future and that drastic changes in driving patterns seem unlikely. Regulating average vehicle fuel economy is the best present means to achieve this end.

We at NHTSA estimate the costs of all of our proposed regulations. However, since the standards are set in terms of performance rather than hardware or design, individual manufacturers are generally free to choose from a number of options to meet a standard—which means that their costs may vary substantially, according to the options they choose and the degree to which they may exceed the requirements of the standard. Nevertheless, it is the manufacturers themselves (who supply wholesale price information to the Bureau of Labor Statistics) who are the prime source of data on the costs of implementing our regulations. On the basis of their data and other available information, the Department of Transportation estimates the average cost to consumers of safety features contained in a model year 1978 automobile at about $250—approximately half the amount claimed by some auto makers and roughly 5 percent of the total vehicle price. Considering the payoff—the General Accounting Office estimated in 1974 that vehicle safety standards had saved some 28,000 lives over the years from 1966 to 1974—safety requirements are one of the car buyer's best investments.

In a 1976 survey of automobile manufacturers, the NHTSA asked the following question: "For each safety standard presently implemented for passenger cars, what will be the reduction in retail price if that standard is revoked . . . ?" Although the manufacturers' responses varied widely (overall reductions ranged from $12 to $385), the sales-weighted average was $80. Yet in response to another question, some manufacturers claimed our standards added $368 to a vehicle's price.

Auto industry executives have been particularly critical of regulations promulgated but not yet effective. These include an upgraded bumper standard, passive restraints, and fuel economy standards for passenger cars and for light trucks and vans. Yet the estimated addition to the price of a passenger car because of these standards will be only about $300 by 1984 (in 1977 dollars), and this will be offset by a more than threefold direct out-of-pocket saving to the consumer in fuel economy, plus reductions in highway casualties. It does not appear to be disadvantageous to the consumer to pay $300 more for a 1984 car than for a 1977 car if that amount would save the consumer $890 over the life of the vehicle. Indeed, because of the heavy travel by newer vehicles, the $300 could be recouped through decreased operating expenses within two years of a vehicle's purchase. And for trucks and vans, the fuel economy standards in particular will result in consumers' spending 6 cents to save a gallon of gasoline that would have cost them at least 65 cents (given our assumptions on vehicle use).

National opinion surveys show that the American people, by a wide margin, support government health and safety standards. In a Harris poll of spring 1978, Americans were asked to rate the importance of nine proposed improvements in the nation's transportation system. Improving auto safety finished far in front—with 83 percent of those polled rating that quest as "very important." Given the size of the job, that popular support provides a good climate for developing what has been called the socially responsible automobile.

But even if it did not—even if the climate were truly poisoned by industry exaggerations of the pernicious effects of government—the benefits of health and safety regulation and of fuel efficiency standards could still, in our view, outweigh the costs. And if the free enterprise system in this country is undermined when we force auto makers to do what the people want and what foreign companies increase their sales by doing, then perhaps our enterprise is itself subject to bureaucratic bungling. Perhaps our corporations are like the shepherd boy who cried "wolf" because he grew tired of tending to his proper business. But this much is clear—it is time for us to answer back. ■

REGULATORY REPORT

The Costs and Benefits of Regulation—Who Knows How Great They Really Are?

Business complains that federal regulations cost more than $100 billion a year, but public interest groups disagree and argue that the benefits outweigh the costs.

BY TIMOTHY B CLARK

"I am not here as a Neanderthal," economist Murray L. Weidenbaum told Rep. Albert Gore Jr., D-Tenn., during a recent congressional hearing on cost-benefit analysis by regulatory agencies.

Gore replied that he did not mean to suggest that Weidenbaum represented a species of prehistoric man. But if critics and supporters of federal regulation aren't calling each other names, they are coming close to it.

Weidenbaum, who last year estimated the cost of federal regulation at more than $100 billion a year, has been accused of "Chicken Little economics," "ideological arithmetic" and "consumer fraud" by Mark Green, director of Ralph Nader's Congress Watch. Weidenbaum in turn has labeled Green's recent study of regulatory benefits a "biased lawyer's brief" that "fails to meet the basic standards of scholarship."

Congress is having to sort through the "biased briefs" and "Chicken Little arithmetic" as it prepares to decide whether federal agencies should be required to balance the costs and benefits of their actions. That will be no easy job, given the slippery nature of the statistics being developed.

On one side, the Weidenbaums of the world, with the devout backing of the business community, are arguing that the costs of regulations—the increased costs that they impose on consumer goods and the depressing effect that they have on the economy—outweigh the benefits.

On the other, the Greens scoff at the high cost estimates and contend that the benefits—if only the value of saving lives and cleaning the environment could be measured in dollars—are worth much more.

In Congress, the Senate Judiciary Committee will soon report legislation requiring agencies to improve the quality of their economic analysis of future regulations. Congress will probably shy away from requiring strict cost-benefit studies, although several bills are pending that would make agencies apply a relatively strict benefit test to new regulatory schemes.

THE MAGIC $100 BILLION

When Weidenbaum produced his $100 billion estimate of the cost of federal regulation, he struck a chord that resonated through the business community. His figures, which he developed at the Center for the Study of American Business at Washington University in St. Louis, have been cited repeatedly.

A newspaper advertisement by Amway Corp., entitled "Regulatory Overkill," declared: "The Center for the Study of American Business estimates government regulation costs a family of four more than $2,000 a year. . . . That's more than 10 per cent of their income."

The National Cotton Council, in an ad called "Over-regulation could cost your family a home of your own," said: "You're being eaten out of house and home by federal regulations. Many of them unreasonable. And all of them costing you money. As much as $130 billion a year or $2,000 per family."

The Chase Manhattan Bank N.A. wrote an ad, based on figures it said were developed by its own economists, that said regulation cost more than $100 billion a year. That drew a rebuttal from Peter J. Petkas, director of the Regulatory Council, which comprises the chiefs of federal regulatory agencies and tries to coordinate their activities. In a letter, Petkas called the Chase figures "unsubstantiated."

It took Weidenbaum, on leave from Washington University this year at the American Enterprise Institute for Public Policy Research, more than three years to arrive at the magic figure of $100 billion in regulatory costs.

His center at Washington University began in 1975 to study capital formation, taxation and labor policy. That year, Weidenbaum published a paper on "Government-Mandated Price Increases" that said government contributed to inflation not only through budget deficits and "excessively easy monetary policy" but also through a "less obvious—and hence more insidious—way"—regulation.

In that study, Weidenbaum did not attempt a guess at the total cost of regulation, but noted that the budgets of some 25 regulatory agencies had risen from $1.3 billion in fiscal 1973 to $2.2 billion in fiscal 1975. The study, boasted Weidenbaum in a recent interview, was "pioneering" and "widely read."

In 1978, he and his associate, Robert DeFina, made what Weidenbaum characterized as a "careful" search of all public and private-sector estimates of the "indirect costs" of regulation—those borne largely by industry. To estimate the costs imposed by the Occupational Safety and Health Administration, they relied on an annual survey taken by McGraw-Hill Inc. The Council on Environmental Quality was the source of their estimates on the costs of environmental regulation. A large number of academic studies were cited as evidence for costs in other areas.

Weidenbaum contends that his cost estimates were conservative. When he could find no compliance cost estimates, for example, for the Consumer Product Safety Commission, the National Transportation Safety Board or the National Labor Relations Board, he omitted them from his total instead of attempting to guess at the costs they impose. When a range of estimates was

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Murray L. Weidenbaum labeled Mark Green's recent study of regulatory benefits a "biased lawyer's brief" that "fails to meet the basic standards of scholarship."

available, Weidenbaum said, he and DeFina usually chose the lowest figure.

The two concluded that in 1976 the categories of federal regulation they studied cost the economy $66.1 billion: $3.2 billion to operate the regulatory agencies and $62.9 billion to comply with their regulations. Federally required paperwork contributed the largest share—$25 billion, as estimated by the Federal Paperwork Commission—followed by "industry-specific" regulation (of the airlines, for example, by the Civil Aeronautics Board), at $19.9 billion. Regulation of energy and the environment, the study said, cost $7.8 billion; consumer safety and health, $5.1 billion; and job safety and working conditions, $4 billion.

Weidenbaum took his next—and most widely questioned—step in April 1978, estimating the cost of regulation in 1979 for the congressional Joint Economic Committee. Instead of assembling new data on regulatory costs, he simply extrapolated from the results of his study of 1976 costs.

Agencies whose budgets totaled $3.2 billion in 1976 imposed compliance costs of $62.9 billion—a ratio of 20-1. In 1979, Weidenbaum found, the regulatory agencies' budgets reached about $4.8 billion, and Weidenbaum multiplied by 20 to reach an estimate of $97.9 billion in compliance costs. Adding the two figures together, he said federal regulation would cost at least $102.7 billion, adding that regulatory costs to business were probably "substantially underestimated."

In his latest book, *The Future of Business Regulation* (American Management Association, 1979), Weidenbaum writes: "The rising tide of regulation has become a major barrier to productive economic activity. The costs arising from government regulation are basic: (1) the cost to the taxpayer for supporting a galaxy of government regulators, (2) the cost to the consumer in the form of higher prices to cover the added expense of producing goods and services under government regulations, (3) the cost to the worker in the form of jobs eliminated by government regulation, (4) the cost to the economy resulting from the loss of smaller enterprises which cannot afford to meet the onerous burdens of government regulations and (5) the cost to society as a whole as a result of a reduced flow of new and better products and a less rapid rise in the standard of living."

The Weidenbaum-DeFina 1978 study drew prompt attacks. In a report dated Sept. 26, 1978, Julius W. Allen of the Congressional Research Service found "serious shortcomings and limitations" in their work.

Allen criticized their 1976 estimates for their reliance on "sources based on data that in some cases go back more than a decade . . . adjusted to 1976 prices using the consumer price index." He also found "unresolved problems of double counting and inaccurate addition."

"Of particular importance," Allen wrote, "is the fact that Weidenbaum and DeFina make no attempt to determine the value of the benefits of regulation, so that a net cost of regulation, rather than a gross cost, could be determined."

Allen concluded that it was impossible to say whether the study's estimate of regulatory costs "is too high or too low, only that it has enough questionable components to make the totals arrived at suspect and of doubtful validity."

Allen also questioned their use of the 20-1 ratio to extrapolate 1976 costs to 1979. He said the justification—that the estimates of 1976 regulatory costs were substantially understated—"is a dubious rationalization for a questionable procedure."

In several attacks on Weidenbaum, who was an assistant Treasury secretary during the Nixon Administration, Green has made many of the same points as Allen. In addition, he has argued that Weidenbaum unfairly lumped the costs of the economic regulation of such industries as the airlines into the same category as the costs of social regulation, whose aims include environmental and workplace health and safety. Economic regulation, he said, is the cost that some businesses must pay for immunity from antitrust laws.

MORE NUMBERS

Another major contribution to the debate came last March, when the Business Roundtable released the results of its year-long study of costs incurred by 48 major companies. The study, conducted by the accounting firm of Arthur Andersen & Co., measured only the "incremental" costs of six regulatory programs—those that the companies would not have incurred in the absence of regulation in the six areas. It found that the incremental costs in 1977 amounted to $2.6 billion, which, if passed directly on to the consumer, would have increased prices of the companies' products by 1.1 per cent.

The Business Roundtable seemed disappointed that the study had produced such a relatively small number. Frank T. Cary, chairman of both the International Business Machines Corp. and the Roundtable's task force on government regulation, said, "The study measured only the tip of the regulatory cost iceberg."

The Roundtable study was quickly seized upon by advocates of regulation, including Green, who triumphantly announced that "there is just no way that the Roundtable's conclusion of $2.6 billion in regulatory costs can be reconciled with Mr. Weidenbaum's $102.7

billion estimate. Since the 48 companies involved are the largest in the country and the six agencies among those most attacked by business, the Roundtable study is more the body of the iceberg than its tip."

The Commerce Department last year attempted to produce its own study of regulatory costs. It employed a consultant, Paul B. Downing, associate professor of economics at Virginia Polytechnic Institute, who reviewed and updated Weidenbaum's estimates for 1976 and concluded they were too low.

By adjusting Weidenbaum's figures and including agencies that Weidenbaum had omitted, Downing calculated that 1976 regulatory costs fell in a range between $82.7 billion and $103.1 billion, significantly higher than Weidenbaum's estimate of $66.1 billion. But the Commerce Department wasn't satisfied with "technical economic points" in the study, said Robert T. Miki, director of the department's office of regulatory economics and policy, and decided this fall not to publish it.

Meanwhile, other estimates of the costs of regulation continue to be produced. In August, the Environmental Protection Agency released a report saying that federal pollution control had cost $23.2 billion in 1977 and would cost a total of $360 billion between 1977 and 1986 — though it added that the benefits are substantial. And Edward F. Dennison, an economist who has worked at the Brooking Institution and the Commerce Department, updated his study concluding that environmental and health and safety regulation significantly dampens industrial productivity.

MEASURING BENEFITS

As Allen has noted, measurements of the costs of regulation are not particularly valuable unless they are weighed against the benefits. But so far, the numbers marshaled by the advocates of regulation have been more suspect than those compiled by Weidenbaum and other critics.

Some studies have at least begun to estimate the magnitude of the damage to society from pollution and the other targets of social regulation.

While meaningful measurements of the benefits of regulation in reducing those damages still seem out of reach, supporters of regulation have been scrambling for new measuring techniques and new numbers.

In August 1978, former Rep. Paul G. Rogers, D-Fla., convened a one-day conference on "the environment and health care costs," one of whose purposes was to emphasize the impact of environmental hazards on health care costs.

"The nation's annual bill for cancer, heart and lung disease alone totals about $100 billion," including loss of earnings from illness and premature death, Rogers said. "We ought to be able to save a portion of this bill by controlling the environmental causes of these diseases. If we could just reduce the incidence of cancer, heart and lung disease by 10 per cent, the savings would be $10 billion per year."

The conference concluded that "policies directed at improving monetary quantification of disease and illness, with particular attention to the economics of prevention, need to be developed."

The Public Interest Economics Center plans a book next March based on a conference in October 1978 on measuring benefits. Center president Allen Ferguson said the book will "try to help people understand the usefulness, the limits and the methods of benefit analysis, and what is needed to make it more useful."

In its report in August, EPA included a chapter on benefits that said that the agency "has never applied comprehensive benefit estimation methodologies to a contemplated regulatory decision." Agency-generated estimates of damages from air and water pollution "have been very crude," the agency said, ranging from $2 billion to $35 billion a year for air pollution and from $5 billion to $19 billion for water pollution.

The agency, however, cited a new study it had sponsored at the University of Wyoming that "may provide significantly more reliable estimates of national morbidity and mortality damages from air pollution than the EPA has had before." The study concluded that many benefits, including aesthetic ones, that are "traditionally viewed as intangible and thereby nonmeasurable can, in fact, be measured." For air pollution, it estimated "national mortality effects" of $5 billion to $16 billion a year and "national morbidity effects" of $36 billion a year.

The Wyoming researchers, who found that chronic illness and lost work days were particularly high in areas with heavy pollution, arrived at their $36 billion figure by estimating the value of the time lost from work. EPA pledged to devote "significant resources" in the next year to improve its ability to measure benefits, adding that it would test the usefulness of applying a cost-benefit approach to developing specific regulations.

Certainly the most voluminous study of regulatory benefits was produced in October by Mark Green and Norman Waitzman, a graduate student at The American University. Issued by Nader's Corporate Accountability Research Group, the 162-page study, "Business War on the Law: An Analysis of the Benefits of Federal Health/Safety Enforcement," is replete with attacks on Weidenbaum and others who have attempted to measure regulatory costs.

"To be complete, benefit measurement must be able to appraise both the value of life and property," Green and Waitzman wrote. "What is the value of being able to see clear across the Grand Canyon? How much is life worth?"

Despite the admitted difficulties in quantifying benefits, the study uses a variety of sources to estimate that five agencies that imposed costs of $31.4 billion in 1978 (according to the Weidenbaum technique) produced $36 billion in benefits in the same year. Benefits would increase to $80.6 billion in 1985, the study estimated.

Green responded by accusing Weidenbaum, who estimated the cost of federal regulation at more than $100 billion a year, of "Chicken Little economics," "ideological arithmetic" and "consumer fraud."

A Look at Weidenbaum's Figures

Using various public and private estimates, economist Murray L. Weidenbaum and his associate Robert DeFina found in 1978 that federal regulation imposed at least $62.9 billion in compliance costs, mainly on business, in 1976. They placed the administrative costs of the agencies at $3.2 billion.

Finding that compliance costs exceeded administrative costs by a factor of 20 in 1976, Weidenbaum applied the same multiplier in 1979 to estimate compliance costs of $97.9 billion and total regulatory costs of $102.7 billion. In an October article, Weidenbaum said fiscal 1980 regulatory costs were likely to total $6 billion — which would indicate compliance costs of $120 billion and total regulatory costs of $126 billion. He declined, however, to publish that extrapolation, saying, "We had hoped that our initial, exploratory effort would have led to some serious work by others on the stability of the regulatory multiplier that we used." But no more research has been done.

Here are Weidenbaum's figures (in millions of dollars):

	1976 Administrative costs	1976 Compliance costs	1979 Administrative costs
Consumer safety and health	**$1,613**	**$5,094**	**$2,671**
Agriculture Department	377	986	830
Health, Education and Welfare Department	218	360	298
Justice Department	167	NA	239
Transportation Department	365	3,748	578
Treasury Department	437	NA	668
Other	49	NA	58
Job safety and other working conditions	**446**	**4,015**	**626**
Interior Department	84	NA	1
Labor Department	230	3,670	409
Equal Employment Opportunity Commission	59	345	108
National Labor Relations Board	67	NA	100
Occupational Safety and Health Review Commission	6	NA	8
Environment and energy	**682**	**7,760**	**1,116**
Energy Department	136	NA	284
Environmental Protection Agency	363	7,760	522
Council on Environmental Quality	3	NA	3
Nuclear Regulatory Commission	180	NA	307
Financial reporting	**97**	**1,118**	**132**
Federal Trade Commission	44	1,000	64
Federal Reserve System		118	
Securities and Exchange Commission	51	NA	65
Other	2	NA	3
Industry-specific regulation	**226**	**19,919**	**277**
Civil Aeronautics Board	91	2,697	96
Federal Communications Commission	53	1,460	66
International Trade Commission	10	4,700	13
Interstate Commerce Commission	47	11,004	69
Other	25	58	33
Paperwork		**$25,000**	
Total	**$3,064**	**$62,905**	**$4,822**

The study provoked a prompt response from Weidenbaum's allies. Weidenbaum himself briefly criticized the study during joint hearings by two Interstate and Foreign Commerce subcommittees, saying, "The saddest aspect of the Nader group report is the great emphasis on vituperation, on the nastiest of personal attacks on scholars with whom they disagree on a given issue."

A detailed critique of the study was produced at the subcommittees' request by James C. Miller III, a resident economist at the American Enterprise Institute and the author of numerous treatises on regulation. Miller leveled a general attack on the "objectivity" of the report and wrote 56 pages of point-by-point criticisms.

DECISION MAKING

Though most of the debate has revolved around aggregate numbers, such as those produced by Weidenbaum and Green, the real issue is this: should individual regulations be allowed only if their benefits outweigh their costs? Not surprisingly, given the difficulty with quantifying benefits, Green and his allies strongly resist such an approach.

A 1976 report by the House Interstate and Foreign Commerce Committee on cost-benefit analysis remains valid today: "The most significant factor in evaluating a benefit-cost study is the name of the sponsor. Benefit-cost studies generally are formulated after basic positions on an issue are taken by the respective parties. The resulting competing studies predictably reflect the respective positions of the parties on the issue."

The truth of that statement can be tested by the history of cost-benefit analysis of federally sponsored dams and other water management projects. By law, the Army Corps of Engineers must prove that the benefits of any proposed project outweigh its costs, and the corps over the years has constructed elaborate methods of assigning dollar values to benefits from hydroelectric power, navigation, flood control, water supply, recreation and protection of fish and wildlife.

The corps has been known to stretch the credibility of its benefit calculations to the breaking point. At one point during the long fight over the $800 million Dickey-Lincoln dam in Maine, for example, the corps attempted to claim benefits for flat-water recreation, though the lake the dam would create would add little to the recreational opportunities already available on more than 3,000 natural lakes in Maine.

The Environmental Policy Center, which makes a practice of challenging water projects, charged that the corps wildly inflated its benefit estimates for the $1.5 billion Tennessee-Tombigbee waterway project in Mississippi and Alabama. It said the corps has claimed navigation benefits for companies that either no longer exist or say they would not use the canal to move their goods.

The Carter Administration, itself a critic of some water projects, last year asked the interagency Water Resources Council to devise new cost-benefit estimating procedures for the corps, the Bureau of Reclamation, the Soil Conservation Service and the Tennessee Valley Authority. Final regulations are expected soon.

In response to mounting concern about the costs of regulation, the Administration has been requiring executive branch regulatory agencies to conduct more thorough economic analyses of proposed rules. Under a March 1978 executive order, agencies must produce "regulatory analyses" of proposed major regulations—those having an annual impact on the economy of $100 million or more.

The Administration has stopped short of demanding strict cost-benefit analyses, aiming instead to ensure that regulations are "cost-effective"—that they accomplish their goals at the least possible cost to the economy. So far, however, OSHA and some other agencies have resisted and the requirement for regulatory analysis has had little impact. *(See NJ, 9/29/79, p. 1596.)*

Similarly, the Regulatory Council has made little headway with a demand that agencies provide an earlier look at estimated costs and benefits in their submissions for the council's semiannual calendar of upcoming regulations. The second edition of the calendar, published on Nov. 28, nonetheless contained significantly more information on regulations under development by the agencies than did the first, Petkas said.

OSHA's longtime resistance to cost-benefit analysis was dealt a setback last year, when the U.S. Court of Appeals for the 5th Circuit threw out an OSHA rule to protect workers from airborne benzene. The court argued that OSHA had not justified the $500 million cost to industry.

"Although the agency does not have to conduct an elaborate cost-benefit analysis, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard," Judge Charles Clark wrote. OSHA's appeal of that decision is to be decided by the Supreme Court in its current term.

COST-BENEFIT NOW?

The Carter Administration has asked Congress to put the force of law behind its executive order of March 1978, which includes the requirement for regulatory analyses. In response, Members of Congress, particularly in the Senate, have written a variety of bills with provisions ranging from strict cost-benefit requirements to a weakened version of the executive order.

The Senate Judiciary and Governmental Affairs Committees are considering both the Administration's bill (S 755) and a similar measure (S 262) sponsored by Abraham Ribicoff, D-Conn., and Charles H. Percy, R-Ill., the chairman and ranking minority member of the Governmental Affairs Committee.

The Ribicoff-Percy bill is considered somewhat weaker than the Administration's on the cost-benefit question. It would not require, for example, that final rules be accompanied by explanations of their economic effect, including the reasons for selecting alternatives to the least expensive approaches. Both bills would seek to avoid judicial review of regulatory analyses in most instances.

OVER-REGULATION COULD COST YOUR FAMILY A HOME OF YOUR OWN.

The National Cotton Council placed this ad in the Saturday Review *last July.*

These measures are much milder than competing measures introduced by Sens. Lloyd Bentsen, D-Texas (S 54), Harrison (Jack) Schmitt, R-N.M. (S 104) and Robert Dole, R-Kan. (S 1979). These bills would establish much stricter standards for cost-benefit analysis, and Dole's and Bentsen's would explicitly provide for judicial review. Dole, explaining his bill on Nov. 2, said "a new regulation could become effective only when an agency reasonably concludes that the benefits of a proposed rule would outweigh its costs and other adverse effects, and when the agency is convinced that the proposed rule is the most cost-effective means to achieve the identified benefits."

In anticipation of Senate action, Green organized a coalition of 26 environmental, consumer and labor organizations that wrote to Carter on Nov. 2, explaining their opposition to cost-benefit requirements. The coalition objected to provisions of the Administration bill that would encourage agencies to adopt the "least burdensome" approach to accomplishing their regulatory goals. It argued against judicial review of regulatory analyses, warning that to provide regulation's opponents with easy access to the courts would be to "turn an economic and managerial tool into a nightmare of excessive litigation."

In the Senate debate, both sides will undoubtedly rely on competing estimates of the over-all costs and benefits of federal regulation. If the rhetoric to date is any indication, the debate will be a hot one.

Weidenbaum's estimate of the high cost of regulation, Green wrote recently, "is shot through with methodological errors, combines incommensurate numbers and rhetorically attacks consumer and environmental regulation when more than two-thirds of its total is attributable to cartel regulation and paperwork."

Weidenbaum, responding to Green and his allies during the hearings by Gore's subcommittee, replied, "I have never known of a self-styled public interest group making any serious effort to find out what the public wants. . . . Perhaps they are so smart that they know what is in the public interest. But I tell you, from my own many years in government, I am always deeply offended by anyone who contends that they represent the public interest."

This much seems sure: the Senate will have a hard time cutting through the rhetoric to explore whether there are any facts behind it. ☐

CONSUMER REPORT

King and Her Court at the Consumer Product Safety Commission

Susan B. King, the commission's new head, believes in government regulation, and she is determined to improve her agency's reputation.

BY LINDA E. DEMKOVICH

Don't let the soft-spoken southern manner fool you. Susan B. King, the new chairman of the Consumer Product Safety Commission, talks with a "get down to business" toughness and determination that let you know she's going to try to restore credibility to the agency and make it work the way the law intended.

The job before her is a big one: to transform the commission, beset by external criticisms and torn by internal strife almost since it was established in 1972, into a productive and efficient agency. So skeptical were some Members of Congress and Administration aides that there were proposals earlier this year to abolish the commission and transfer its functions elsewhere.

King, whom Carter named to the commission in January and elevated to the chairmanship in June, had no background in the consumer safety area, a fact that had some people on Capitol Hill worried. King said it worried her a bit too, but no longer.

"My background is not science or engineering, but everybody that I talked to said that what the commission needed now was a strong infusion of common sense," she said in a recent interview.

The 38-year-old Georgian gained administrative experience as executive assistant to the chairman of the Federal Election Commission, executive director of the Center for Public Financing of Elections and Washington director of the National Committee for an Effective Congress. That may help her to solve some of the management problems that have kept the agency from functioning smoothly.

King is a strong believer in the regulatory process. "I get very upset when I hear this mounting criticism of government regulation as the source of inflation and something that the public doesn't want," she said. "It is fallacious and somewhat demagogic in its attack; it detracts from a lot of other serious problems of inflation and does not acknowledge the difference between good regulation and bad regulation."

And she is not at all reluctant to point the finger of blame: "What I see is a powerful segment of the business and industrial community trying to turn a general irritation with government into a specific attack on health and safety regulations."

King said that Congress's decision to reauthorize the commission for three more years gives it a "lease on life." But she must also be aware that if she fails to turn things around, the lease may not be renewed.

Edited excerpts of the Oct. 17 interview follow:

Q: What shape was the commission in when you arrived? Do you intend to do any further reorganizing?

A: Without question, the organizational structure and management procedures of the commission were improved very considerably by [former] chairman [S. John] Byington. There must have been next to nothing in place when he took over. But it takes longer than two years to deal with some of these problems, and we are still having to contend with problems which originated with the original organizational staff and structure.

In addition, I think it's fair to say that the mission of the agency has also changed, so that the needs of the agency probably would be differently defined now. By that I mean an emphasis on chronic hazards, carcinogens in particular.

As to the structure as I found it, I told OMB [the Office of Management and Budget], which had originally talked about attempting to abolish the commission, "All right, if you really want to put your swords away, let's have some constructive and serious help." I was concerned not with personnel, not with staffing, but with systems, organization and management systems. They agreed with me that the things that I was worried about were the largest problem areas: inadequate delegation of authority to staff, inadequate direction from the commission and a need for greater accountability on the part of the staff. They agreed the structure was basically sound and with some streamlining of the systems, we could address the major problems. That doesn't mean there will be no changes. But in terms of the basic structure of the organization, no.

Q: Have those minor changes taken place?

A: They're moving along. The most serious problem that I inherited was the lack of adequate personnel management. It's almost impossible to begin to address specific actions or even minor readjustments or fine tuning that you want to do until you can take a picture of your organization at a point in time.

Q: What are the commission's priorities?

A: There are three or four areas in which we're interested. One is to conclude action, one way or another, on a number of matters which have been pending for far too long. We have got to wrap some of these up. Power mowers is one. Christmas tree lights is another. Second, I am very interested, and I think the other commissioners would agree with me on this, in trying to shift the focus of the commission to much stronger emphasis on potentially serious hazards that are unforeseeable or unavoidable in nature.

Q: Such as?

A: Aluminum wiring. That is not something that an average consumer is going to know a great deal about. The type of

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wiring in his home, the kind of hazard it causes, how to address it if they do have a problem. Smoke detectors. People install them and don't know a great deal about them. Home insulation. So we're talking much less about the traditional household product.

Q. What else?

A. There has been a long-standing interest in children's items [such as] skateboards. We recognize that it's probably not intelligent at this point for an agency to try to move with a regulation against skateboards, because 98 per cent of the injuries are user-related and have nothing to do with the product itself. So there is tremendous emphasis on information and education.

The fourth area I would say would be energy: home insulation, energy conservation devices.

People do want protection in these areas. I think if you were to draw up a list of things that this commission had done or OSHA [the Occupational Safety and Health Administration] or EPA [the Environmental Protection Agency] had done and ask people if they want government out of these areas, the answer would be no.

Q. One of the areas where the commission has been criticized is the slowness with which standards are developed.

A. Who has become very artful in delaying tactics? There are high-priced lawyers and trade associations in this town who spend their entire time doing the same thing at regulatory agencies as they do in the courts. At the same time, they scream when anybody wants to talk about meaningful public participation.

ALTERNATIVES TO REGULATION

Q. Is there any alternative to writing standards? How about education and information programs?

A. Information and education means changing behavior, and it's a very long and involved process. It would seem quite apparent that people know a power lawn mower is a dangerous object, but there are 60,000 hospital-treated injuries a year. You can put all the labels in the world on a power lawn mower and you've not told them anything that the user of the mower did not already know.

There have been a lot of discussions about how to use tax incentives, tax penalties, information and education programs, a variety of other mechanisms. But in some areas, I think the hazard is severe enough and the economic cost of nonregulation high enough that there probably is no alternative to regulation.

Q. How about voluntary compliance?

A. We're trying to develop a very intensive working relationship with the chain saw industry to see if the development of a kickback remedy, which is the highest source of accidents, can be worked out in the voluntary mode. But we're not to the hard part of the standard yet. And the chain saw industry is different. It's small, there are only 11 manufacturers, they're all faced with a problem that for them is serious. When you're dealing with a multitude of manufacturers across a given industry, you can't police a voluntary standard.

Q. How is the public participation program going?

A. We're in the process now of formalizing that effort. The real interest is being sure that any public participation effort is clearly defined. The purpose of it is to allow views to be represented that could not otherwise be represented. The great inequity in this whole rule-making process is that business groups and trade associations have a great deal of money at their disposal to take part in proceedings and make their views well known. Not only do they have the money to do it, they deduct it as a business expense. And consumer groups and individuals and maybe even small businesses may not have the funds available to do it.

Q. How much money are you spending on the program?

A. Very little to date. We envision a small operation, two or three people, mainly an outreach operation. We want to be sure that all views are represented.

Q. What is the commission's role in developing a national cancer policy?

A. The commission published an interim policy for screening and classifying potential carcinogens in consumer products. There's a regulatory continuum on carcinogens: FDA [Food and Drug Administration] dealing with food and drugs and medical devices, OSHA in the workplace, EPA in the environment and CPSC in product areas. Everyone is dealing with the same substances. The real concern of the commissioners and the staff was that this could be a very significant area that would not receive the attention it deserved if it were left to other agencies. For example, asbestos: nobody was addressing it as it might be involved in a consumer product.

GETTING ALONG WITH CONGRESS

Q. What is the relationship with Congress now? Have Sen. Wendell H. Ford, D-Ky., chairman of the Commerce, Science and Transportation Subcommittee on the Consumer, and Rep. Bob Eckhardt, D-Texas, chairman of the Interstate and Foreign Commerce Subcommittee on Consumer Protection and Finance, given you any specific directions?

A. They have been very, very supportive of the commission, without telling us specifically what the commission should do other than I think something that's understood by all of us, which is get moving, stop the silliness, and be able to justify what you do. It's sort of a common sense directive that we have had from them. They believe that an agency is needed, that the hazards are certainly there to be dealt with.

Susan B. King: "I want to be fair."

Q. A lot of people, including Ford and Esther Peterson, went out on a limb for the commission. . . .

A. They sure did, and we're very conscious that it's up to us now to produce. The three-year reauthorization really is a lease on life for the commission. It's sufficient time to make the transition in leadership.

Q. What is the relationship among the commissioners now?

A. Excellent. We really want to get the trust level up. I think that's terribly important. A collegial body can function only if the commissioners can work together. If the commissioners are fighting each other, all the best staff work in the world can't overcome that terrible problem at the top.

Q. How is your relationship with industry?

A. I'm not hostile to them. I spend a lot of time talking to the business people. They know that I'm very critical of them but when they're being straightforward, they're free to admit that there are very bad actors in the area who have done some very bad things which give everybody a bad name. I want to be fair. I'm by no means anti-business. But I'm very critical of what I think is oftentimes irresponsible and recalcitrant foot-dragging on the part of business groups. ☐

PRODUCT SAFETY: DIMENSIONS FOR CONSUMER POLICY

Alvin S. Weinstein

Introduction

A sensitized society and the law of strict liability are social phenomena that have erupted as two peaks to be scaled by technology in reaching a societally acceptable policy for balancing risk and utility.

Where once society believed implicitly in technology's ability to solve all problems, the technological community is now held to be the inept midwife filling our lungs with pollutants, our stomachs with toxic chemicals and maiming us with unsafe products.

Regardless of how pervasive these charges are, it is clear that we are searching for guideposts which permit us to chart new directions in improving the quality of life.

There is no doubt that societal mores can be readily sensed by policy makers, yet they provide, at best, only vague guidelines for the decision-making functions. The legal thrust of strict products liability, however, offers a clearer picture of a desirable objective for social policy: products must *not* be unreasonably dangerous. We have literally made a legal about-face in the last two decades. From the historic rule of caveat emptor--let the buyer beware--the challenge is now caveat venditor--let the manufacturer beware! It is from this altered perspective that we begin to probe the directions for product-consumer equity.

The premise explored here postulates, quite simply, that the basic philosophy of the law of strict liability offers a matrix upon which to construct sound public policy for the interaction of technology and society. The law indicates the appropriate questions to be answered and suggests the directions for meaningful efforts in resolving the difficult issues.

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The Legal Premise

The California Supreme Court, in a 1963 decision, established strict products liability--a statement of social policy whose impact has traumatized the manufacturing community. The court stated, in part, in the decision rendered in Greenman v. Yuba Power Products:

> A manufacturer is strictly liable...when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury.
>
> The purpose of such liability is to insure that the costs of injuries resulting from such defective products are borne by the manufacturer that puts such products on the market rather than the injured persons who are powerless to protect themselves.

The social policy, enunciated with unmistakable clarity, which emerged from this opinion was, by 1965, delineated concisely as a new legal theory in section 402A of the Restatement of Torts (Second). It provides:

1. One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
   - a. The seller is engaged in the business of selling such a product
   - b. It is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
2. The rule stated in subsection 1 applies, although
   - a. The seller has exercised all possible care in the preparation and sale of his product
   - b. The user has not bought the product from or entered into any contractual relation with the seller.

In the succeeding years over 45 jurisdictions in the United States have adopted section 402A, either explicitly or in somewhat altered forms still preserving the basic philosophy. The injured plaintiff need now only establish that a flaw in the product created an unreasonably dangerous condition (a defect) and that this condition was the most probable cause of the injury.

The manufacturer's care either in the basic design of the product or in its production is of no importance in litigation. No longer is it necessary to demonstrate that a manufacturer did not act "reasonably," or was negligent, for a plaintiff to recover. He need only prove that the product was defective, that is, unreasonably dangerous and that the injury was a direct result of this condition of the product.

The Unreasonably Dangerous Product

What is an unreasonably dangerous product? A product is after all an object, a thing. How does it become unreasonably dangerous? Perhaps it is important to stress the obvious at this juncture. In deciding whether or not a product is unreasonably dangerous we are focusing in on the product and not on the conduct of the manufacturer. In order to develop the issue of unreasonable danger, it becomes crucial to understand not only the scope of consumer expectations but also the entire milieu of product use--the total environment in which the product finds itself.

When, through the litigation process, a jury is asked to conclude whether or not a product is unreasonable dangerous, the decision should have major social and societal significance. Since the legal focus is on the product within its environment of use, the test for unreasonable danger must derive from the elements of risk-utility balancing. It is this balancing process that is central to public policy determination, as well as to the legal forum. It is on the elements of this process that we direct our concerns.

A particularly appropriate view of these elements has been set forth by Dean Wade (Strict Liability of Manufacturers, 19 Sw. L. J. (1965)):

1) The usefulness and desirability of the product
2) The availability of other and safer products to meet the same need
3) The likelihood of injury and its probable seriousness
4) The obviousness of the danger
5) Common knowledge and normal public expectation of the danger (particularly for established products)
6) The avoidability of injury by care in use of the product (including the effect of instructions and warnings)
7) The ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

It is the subjective amalgam of these seven elements, we submit, that can permit a jury to reach the conclusion of whether or not a product is unreasonably dangerous and hence establish "product liability." Consider the following example to illustrate the central issues which should be raised when the issue of unreasonable danger is addressed from the perspective of risk-utility premises, implied by the seven indicia.

There is no question that a kitchen knife is dangerous. It will slice a finger as easily as rib steak. But is a knife defective? That is, is it an unreasonably dangerous product? We approach the answer by considering the issues highlighted by the indicia.

There is no question of the overwhelming utility of a knife. It is a fundamental implement. While fingers may be a safer product, they hardly come close to meeting the same need.

The probability of injury is quite high, while the seriousness of those injuries, in general, can be classified as moderate to low. Even though knives are used by a large fraction of the public, ranging from youth to old age for both sexes, there is common knowledge, as well as expectation of a danger that is highly obvious.

In fact, because the danger is held to be widely recognized, knives do not contain warnings and the incidence of injury can be significantly lessened by care in the use of the product.

Finally, despite the wide recognition of the danger by the public and the moderate seriousness of injuries, we still ask if there is any way to design out the high risk of injury. Unfortunately, technology has yet to discover a cutting edge that can successfully distinguish between a side of beef and a finger.

Thus, in weighing all of these considerations, we would most likely conclude that, on balance, the utility of the knife exceeds the risk. That is, we are willing to subject ourselves to those risks in order to receive the benefit of the product. On balance then, while the knife is a dangerous product, it is not unreasonably dangerous.*

It is suggested that the issues described in this scenario are the same ones that should be raised by both sides in the courtroom.

The thrust of litigation, then, within the framework of strict liability should be, in each case, to distinguish between products which are reasonably safe and those which are unreasonably dangerous. Unless a manufacturer is able to demonstrate that the consumer either unforeseeably misused the product or knowingly assumed the risk of using an apparently defective product, he is liable to the injured party for having produced a defective product because it was unreasonably dangerous.

Given the trade-offs which are inherent in every design, it is suggested that the jury must really answer the question: Given the risk-utility or benefit-cost considerations, are we willing to live with the product as is, with all of its attendant risks, or do we wish it to be marketed in an altered, less dangerous form?

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*It should be noted that even if there were a technological breakthrough that might lessen the risk of knife injuries, we would still have to ask whether such a feature would lessen the utility of the product or substantially increase its cost. If the utility were lessened and the price increased, we might argue that we would prefer to leave the product as is.

Public Policy and the Reasonably Safe Product

If the question posed above is the critical one in the litigation setting for distinguishing between the reasonably safe product and the unreasonably dangerous one, isn't it also the same one that society must ask in formulating public policy for consumer product safety? Fundamentally, since no product can ever be completely safe, and since we have not yet decided on a policy of absolute liability, then our goal is to seek the methodology for deciding the risk level we can tolerate for each product.

This is the challenge which has resulted from the converging concerns of consumers and the enhanced perspective of the courts. The objectives are clear: to educate the consumer, realistically, in understanding the utility and the risks of products; to guide industry in order that products are designed and marketed anticipating real use and not intended use; and to aid the legal system in describing the appropriate considerations necessary for fair and reasonable adjudication of the issues brought before it. These objectives should become part of the province of public policy research.

It is suggested that an appropriate focus is to utilize, prospectively, during the product design process and in the formulation of product safety standards, the risk and utility indicia used by the courts retrospectively in determining the existence of an unreasonably dangerous product. If it is reasonable to assume that these indicia will form the basis for judging the interaction of technology and society in the courts, then it is obvious that these should be the same criteria to be used when products are designed and marketed and when standards or codes are devised for establishing guidelines of design and manufacture.

While deceptively simple to understand and while their intent and meaning cannot be ignored, these indicia, however, do not provide a firm basis for quantitative evaluation. Even if it were their task, the courts are not equipped to establish the groundrules for the important societal judgments that are implicit in testing any product against those indicia.

It does not necessarily follow that those responsible for design, manufacture and marketing are the only ones able to interpret the societal judgments implicit in the search for reasonably safe products. While there is no question that technology must exercise a conscious effort to enhance the decision-making process in design and manufacture, that process must enlist the perspectives and judgments of others to balance, counter, and expand the traditional constraints of industry.

Implicit in the indicia for reasonable safety is the fact that it is no longer the manufacturer's view of intended product use that will be tested in considering a product flaw and its danger, but rather it is the expectation of the consumer that underlies the judgment. The safety of a product must be measured as a balance of the probability of benig harmed, the gravity of the harm if it occurs, and the burden of precaution against the harm. If, for a certain product, both the probability and gravity of the harm are low, while the burden of precaution is high (i.e, the cost of adding additional safety features or impairing the usefulness of the product if the harm is to be avoided), then society may decide that because of an inherently high utility in the product, the added cost produces insufficient benefits and hence the product is safe enough. On the other hand if the cost is relatively small to reduce a harm with high probability and gravity, then society would demand the safer product.

These kinds of judgments cannot be made as generalizations. They require serious consideration for each situation in order to make some type of quantitative cost-benefit analysis. The decisions will be difficult and will require the efforts of those whose research focuses on public policy. The implication in the balancing process between the existence of a harm and the precaution against it is that there is an acceptable risk level below which there need not be any precaution. While this is a valid generalization simply because nothing could ever be completely safe, decisions which permit residual risk of injury to be balanced against objective cost decisions are difficult to make in any event but especially so when they have to be made subject to public scrutiny.

When the reference point for probability and gravity of the harm has to be made, not from the manufacturer's point of view but rather from the consumer's perspective, the gathering of substantive data for decision-making becomes that much more difficult. Surveys that focus on the understanding of a product in the context of its actual environment of use are essential to insure meaningful feedback to govern design modifications.

There is a critical need for devising techniques that can warn, instruct and educate the consumer effectively for reducing the risk level in the use of a product. The techniques that permit decisions to be made between consumer education and design modifications to achieve that same reduction in risk level are not easy to quantify, but obviously must be developed.

There are other concerns, as well. An essential dimension in achieving product safety are standards for design and manufacture. Both the voluntary groups and the regulatory agencies are seeking better methods for developing standards. The problems are not different from those in actual product design. How should the process be structured? What data and techniques should be used for hazard and risk identification? How can the concerns and abilities of the participants best be introduced and woven into the process? What are acceptable risk levels? Should the requirements be those of design and/or performance?

The legislatures of several states are now considering bills that would seriously limit or eliminate the basic social policy contained in the philosophy of strict liability. The enactment of this legislation would be a serious error. While there may be legitimate concern over the inconsistency of awards to injured plaintiffs as well as to current litigation procedures, these are not symptomatic of fundamental problems with the public policy articulated by the law. Rather, they suggest a need for better understanding and implementation of methodologies for establishing a reasonably safe environment for society. It is thus argued that efforts to resist and counter these suggested legislative changes must be undertaken as a public policy objective.

Underlying this discussion is the premise that appropriate risk allocation is the fundamental determinant of public policy. Each segment of society from the producer to the user, including the government, must recognize the risks each is to assume and the risks to be assumed by others.

What is being suggested is a modified and expanded set of constraints that reflect directions for research. They are difficult to quantify and may require enlisting or developing new skills, but they must be undertaken, nevertheless. The government's response to society's demands are patently evident and the legal system has a new set of rules, in strict liability, that are still unfamiliar but place a significantly greater burden on those who enter the market place. The reaction to these stimuli must be positive, incisive and responsive to a new era of understanding our technology in the context of its actual environment and use.

It is suggested that the new directions for emerging technologies, rather than being stifled by government or legal restrictions, will in fact be more challenging because of them. The problems are undeniably more difficult. The research efforts must therefore be more creative and imaginative.

Our views must expand first to recognize that the additional constraints of societal expectations and behavior should be a logical and intimate part of our activities. We must also assume a responsibility for educating the public, assisting the producers, and counseling the legal system as we seek to understand the real interaction of society with technology.

The benefits will be twofold: our products will be better understood by the producer as well as the consumer, and they will better utilized. At the same time, the governmental overseers, the industrial community, and the legal system will benefit by serious attempts to understand and design for society's use of its wares. The guidelines will be brought into sharper focus and the result will be coherent public policy.

The CPSC Experiment

Pitfalls of Hazard

BY THOMAS BICK AND ROGER E. KASPERSON

This article is the third in a series dealing with the problems of hazards and hazard management. In the first article the full range of hazard impacts and consequences was explored. In the second, some thorny generic problems that beset hazard management were discussed. The present article is the first of several case studies focused on the federal regulatory effort. In treating the Consumer Products Safety Commission it surveys the problems of one of the newest and most innovative regulatory agencies. Later articles will focus on other case studies, as well as on the theoretical issues they raise. Much of the work to be included in the series has been or is being done at Clark University by the Hazard Assessment Group or individuals and organizations associated with it.

CHRISTOPH HOHENEMSER
ROBERT KATES
Series Editors

WHEN THE CONSUMER PRODUCT SAFETY COMMISSION opened its doors in 1973, it was hailed by the American consumer movement as a powerful new instrument for creating a healthier, safer household environment. Established by the Consumer Product Safety Act of 1972, the new agency was to be open and accessible to the public, insulated from outside political interference, and with authority over a broad range of products, most of which had been previously unregulated.

Today the CPSC's early supporters look back on the agency's first five years in bitter disappointment. Representative John E. Moss, a leading advocate of the Commission in 1972, recently called the agency "one of his biggest disappointments" and characterized its performance as a "miserable record."[1] Spokesmen for industry and consumer groups alike joined the chorus of criticism, some even going so far as to call for the dismantling of the Commission.

A Twofold Experiment

The CPSC experiment is twofold: it constitutes both an effort to control a broad range of technological hazards and an ambitious attempt at regulatory reform.

The CPSC is empowered to intervene in a broad sector of the private economy to combat the hazards associated with a vast range of products. In this respect the act is part of a general trend in federal hazard management, one reflected in other recently enacted federal health and safety laws. As with current regulatory efforts in the areas of air and water pollution, occupational health, and toxic substances, the CPSC's mission is enormously extensive and complex: the hazards it seeks to combat are highly varied and often poorly understood, while the potential impacts of its actions on the nation's economic health are great. It has been estimated that the CPSC's regulatory domain embraces more than 10,000 different types of products, more than two and one-half million firms (almost half of all U.S. businesses), an annual toll of 30,000 fatalities, 16 to 21 million injuries, and $5.5 billion in product-related injury costs.[2]

As daunting as this breadth of mission is, it is the degree of regulatory reform embodied in the legislation creating the agency that makes the CPSC experiment unique. The congressional sponsors of the act sought to establish a model of regulatory reform—an agency which would be powerful yet open, its broad authority constrained by the active participation of industry and consumer groups in its regulatory processes. It was to be the

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Management

most accessible bureaucracy in Washington, yet at the same time insulated, as no agency before it had been, from politically motivated pressure and manipulation. To this end the Commission was conceived as an arm of Congress rather than an extension of the Executive Branch, so that its day-to-day operations would be independent of the political vagaries of the White House.

How It Works

The Consumer Product Safety Act established four major goals for the agency:

- protecting the public against unreasonable risks of injury associated with consumer products;
- assisting consumers to evaluate the comparative safety of consumer products;
- developing uniform safety standards for consumer products and minimizing conflicting state and local regulations;
- promoting research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

To accomplish these objectives, Congress provided the CPSC with an unusually broad and potent set of regulatory tools.[3] The agency can, for example, issue mandatory standards, require industry-financed testing procedures, ban, or require the recall of products, direct that consumers be notified of hazards, specify labeling requirements, seize and destroy hazardous goods, require manufacturers to provide performance data, and inform the public of the comparative safety of products within different categories. CPSC may enforce its rules and orders by seeking stiff civil or criminal penalties against those who fail to comply with its regulations.

For the most part, only the requirement that CPSC's rules be "reasonable" (a test that makes court challenges to the rules on non-procedural grounds extremely difficult) limits this wide-ranging authority.[4] While the agency is required to consider the economic impacts of its actions, there is no legal requirement that such impacts be the decisive factor in the choice of whether, or how, to act.

Organization

The CPSC is headed by a Commission composed of four commissioners and a chairman. A majority vote of the commissioners is required for all major decisions; it is thus a "collegial" body. It is also a "matrix" organization in that it has both program and functional units. The Office of Program Management is divided into eight "program areas": fire and thermal burns, electric shock, acute chemical and environmental hazards, chronic chemical and environmental hazards, tools and housewares, structural hazards, toys, and sports (with the latter four collectively designated as "mechanical hazards"). The functional units are organized into five directorates: hazard identification

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Susan Bennett King, chairman of the CPSC, calls her new position "the hottest seat in town."

and analysis, engineering and science, compliance and enforcement, field coordination, and administration. Each directorate is divided into "teams," corresponding to the eight program areas. The organizational structure is a "matrix" in the sense that each team member answers to two supervisors—the program manager of the team, who coordinates hazard strategy formulation, and the head of the functional unit, who is responsible for hiring, firing, and quality control.

Managing the Hazards

Hazard management by the Commission involves a number of steps (Figure 1). First the CPSC identifies the most frequent and severe product-related injuries and determines their causes. This is done primarily through the National Electronic Injury Surveillance System (NEISS), a network of telecommunications terminals located in the emergency rooms of 119 statistically representative hospitals across the country. In-depth investigations of injuries (4,000 to 5,000 investigations yearly) and screening of death certificates, consumer complaints, controlled laboratory tests, and data furnished by other agencies supplement this information. In addition, any interested person or group discovering a product hazard may petition the Commission to initiate a hazard control action.

Next the Commissioners (as of 1977) arrange product hazards into priority groupings. Once priorities have been established, strategies for managing the high priority hazards must be formulated. The hazard is assigned to one of the eight program areas. The program manager, in developing a management strategy, utilizes technical expertise from the various CPSC directorates. When all this information and analysis has been sifted and assessed the program manager prepares a "briefing package" summarizing the information and proposing one or more management strategies, listing the pros and cons of each.

The Commission reviews the briefing package, chooses a particular strategy, or returns the package for further work. Not uncommonly a briefing package appears before the Commissioners several times before they make a final strategy decision. If the decision is to promulgate a safety rule (a standard or ban), they initiate rulemaking procedures. If, however, a public education strategy is chosen, the staff prepares an information and education plan.

After a control strategy is implemented, the Commission evaluates its effectiveness. The Directorate of Hazard Identification and Analysis monitors the agency's injury reporting sources to gauge the injury-reducing impact of the managerial strategy. Meanwhile, the Directorate of Compliance and Enforcement determines the extent of industry compliance.

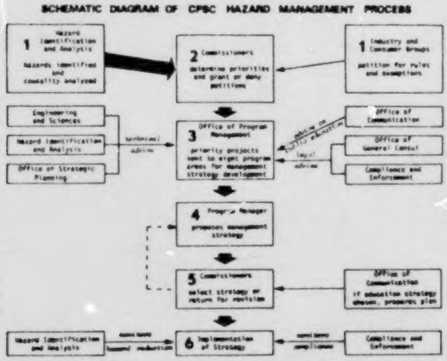

SCHEMATIC DIAGRAM OF CPSC HAZARD MANAGEMENT PROCESS
1 Hazard Identification and Analysis
hazards identified and causality analyzed
2 Commissioners
determine priorities and grant or deny petitions
1 Industry and Consumer Groups
petition for rules and exemptions
Engineering and Sciences
Hazard Identification and Analysis
Office of Strategic Planning
technical advice
3 Office of Program Management
priority projects sent to eight program areas for management strategy development
Office of Communication
advice on public education
Office of General Consul
Compliance and Enforcement
legal advice
4 Program Manager
proposes management strategy
5 Commissioners
select strategy or return for revision
Office of Communication
if education strategy chosen, prepares plan
Hazard Identification and Analysis
monitors
hazard reduction
6 Implementation of Strategy
monitors
compliance
Compliance and Enforcement

FIGURE 1. Schematic diagram of the CPSC hazard management process. The flow of decisions proceeds from stages 1 through 6, as indicated on the diagram. To initiate action the Commissioners receive input from hazard identification units within the agency or from industry and consumer groups on the outside. When a decision is made to take action, the issue is passed on to the Office of Program Management, which deals with the problem via the matrix organization described in the text. This eventually leads to a proposal for action that goes back to the Commissioners, who may decide to implement the proposal or return it to the staff for revision. In the last stages of the process, the Office of Communication and the Office of Compliance and Enforcement may enter the process as needed, either to prepare educational materials or to monitor and enforce compliance with a completed ruling.

Public Participation

The CPSC has two important public participation features—the "offeror" and the citizen petition processes.

The "offeror" process is unique to the CPSC. Section 7 of the Act requires the Commission, when it decides to issue a product safety standard, to announce this intention publicly and to invite any interested person to submit an existing standard for adoption by the CPSC or to offer to develop a standard. The CPSC must accept one or several of these offers if the "offeror" is technically competent, is capable of developing an appropriate standard within a specified period, and agrees to comply with the procedures (including public participation) specified by the Commission.[5] The Commission then reviews the proposed standard prepared by the offeror and, after analyzing its estimated economic and environmental impacts and its hazard-reducing potential, either adopts, amends, or rejects it. If there are no qualified offerors or if the only acceptable offeror represents the industry to be regulated, the Commission may develop its own proposed standard. Once a standard is adopted, anyone may request judicial review of the standard within sixty days.

In addition, the Act provides for early public participation in its decisionmaking via the citizen petition process. Such a petition must set forth the facts supporting the need for a rule and a description of the rule sought. The Commission may deny the petition unless it seeks to regulate a consumer product that "presents an unreasonable risk of injury" and the denial "unreasonably exposes the petitioner or other consumer to a risk of injury."[6] The petitioner, however, may challenge such a denial in court.

CPSC Performance

Despite its broad regulatory powers and the early enthusiasm of its sponsors and staff, the Commission has developed a reputation as a poorly run, unaggressive, and largely ineffectual bureaucracy. A 1976 House oversight committee report spoke for many of the agency's critics when it concluded that, after three years, the Commission had not utilized its broad regulatory powers, had been slow to develop safety standards, and had "yet to demonstrate its capacity to plan, to prescribe administrative rules and guidelines, and to set clear priorities."[7] Hearings held in the House and Senate in 1977 and 1978 further highlighted the failures and deficiencies of the agency. In 1978 the President's Office of Management and Budget (OMB) indicated its intention of seeking to have the Commission abolished. To what extent does the record support the negative assessments of so many of the CPSC's observers?

It is important to note at the outset that the Commission is not without its positive achievements. Most observers would agree that the agency's open door policy has made it a model of a publicly accessible bureaucracy. Most of its meetings have been open to the public and, unlike the situation in most other federal agencies, Commission policy has made disclosure of its records the rule rather than the exception. Even many of the Commission's most vocal critics agree that its system of injury surveillance is among the best hazard identification systems in the country. Most also agree that the actions the Commission has taken in requiring industry to notify it of substantial product hazards have also been successful. In its first two and a half years, the Commission processed 350 notifications from manufacturers, resulting in the correction (largely through informal negotiation) of four million defective consumer products.[8] The product standards and bans issued as of January 1, 1978, though criticized by many as too few and too weak, could ultimately prevent an estimated 553,600 annual consumer injuries (Table 1) and thousands of deaths.

Finally, the continuing threat of federal regulation has undoubtedly led industry to impose safety product standards of its own, although the actual extent of such action is, of course, not known. The consumer product industry is also well aware that a growing number of private attorneys are using the Commission's injury data to help win product liability suits. This is an unpublicized but important contribution of the hazard identification system and may well prove one of the Commission's most significant impacts on product safety.

As significant as these achievements are, they are more than matched by the agency's many deficiencies. The Commission has in the past consistently backed away from forceful regulation. Thus far it has enacted only eleven standards and bans. The first safety standard did not become effective until some three and one-half years after the Commission opened its doors for business; even worse, the standard was for swimming pool slides—hardly a product at the top of the average consumer's "most hazardous" list. To add insult to injury, a federal appeals court recently invalidated most of the standard on the basis that it was unsupported by the evidence available to the Commission.[9] The Commission has repeatedly opted for less controversial labeling requirements whenever its staff has proposed standards or bans. It has almost totally neglected one of its most important responsibilities—to provide consumers with comparative information on the safety of specific products. Despite explicit authorization in the act, the Commission has failed to promulgate

Table 1

ESTIMATED SAFETY CONTRIBUTION OF 8 CPSC REGULATIONS*

Product	Estimated Annual Injuries (in thousands)	Type of Standard Envisioned	Estimated Injury Reduction (in %)	Estimated Product Life** (in yrs.)	Ultimate No. of Injuries Prevented (in thousands)
Architectural glass	464.9	MSR***	70	30	325.4
Bicyles	1,211.5	MSR	17	7	208.0
Matchbooks†	24.1	MSR	20-30	4	4.8-7.2
Refuse bins	28.4	Ban	48	10	13.6
Fireworks	15.6	Ban & MSR	50	1	7.8
Pacifiers	N.A.	Ban & MSR	30-70	1	N.A.
Cribs	23.5	Ban & MSR	20	10	4.7
Swimming pool slides††	N.A.	MSR	N.A.	N.A.	N.A.
Total	1,768.0	-	-	-	563.6

* This table does not include two standards, for baby rattles and cellulose insulating materials, that became effective on August 21, 1978 and September 8, 1978, respectively; nor does it include a ban on self-pressurizing products containing vinyl chloride that became effective in June 1978.

** Product Life provides an estimate of the time required before maximum injury prevention possible is achieved.

*** Mandatory Safety Rule.

† Estimates do not reflect the impact of a recent court decision [D. D. Bean and Sons v. CPSC, —F.2d—(1st Cir., March 31, 1978)] invalidating some parts of the match book standard.

†† Most of this standard has been invalidated by the courts. See note no. 10.

rules requiring manufacturers to keep records, submit reports, or provide performance and technical data.

So far the agency has utilized one of its most important powers—its right to move against "imminent hazards" under Section 12—only four times. Further, the Commission failed to develop until this year a policy for dealing with chronic hazards (products having health effects that show up only after prolonged exposure to the product or after a long latency period following exposure). As a result of this delay the Commission's management of chronic hazards has been beset by confusion and ad-hoc responses. For example, despite overwhelming evidence of carcinogenicity and the receipt of formal citizen petitions for action, the Commission waited for over a year before banning TRIS in children's pajamas and more than two years before banning asbestos in patching compounds and fireplace logs. A chronic hazards policy has now been adopted by the Commission but is currently being challenged in the courts.

In short, the record more than justifies the disappointment of the Commission's founders and supporters. Though recent signs point to a revitalized, more activist Commission (see Box, p. 41) the agency must, on the whole, be considered a failure. What explains the magnitude of this failure and what lessons can be learned which may be applicable to other efforts at federal hazard control?

False Explanations

The citizen petition process was blamed by the Commission's first chairman, William Simpson, for much of the agency's misplaced effort during its first three years. The former Chairman claimed that he interpreted Section 10 as giving the CPSC no choice but to grant any citizen petition seeking the regulation of *any* unreasonably hazardous product. This predicament, he alleged, led to a petition domination of hazard management and a consequent lack of the resources needed to regulate the many "high-hazard" products not the subject of petitions.[10]

However, during Simpson's tenure, as now, the petition process consumed only a small portion of the agency's total resources. Furthermore, the CPSC responded to relatively few petitions in its first three years—leaving a huge petition backlog that has only recently been reduced to manageable proportions. In addition, neither the language of the act nor its legislative history support Simpson's interpretation of Section 10.

The collegial nature of the CPSC (whereby decisions are made by the five-member Commission rather than a single administrator) has also been blamed for many of the agency's shortcomings.[11] However, it is noteworthy that other collegial bureaucracies, such as the Securities and Exchange Commission, are among Washington's most efficient regulators. While some of the CPSC's regulatory delays could perhaps have been avoided had the agency been under the leadership of a single administrator, most of the rulemaking sluggishness and mismanagement that has plagued the CPSC occurred at the staff level, before proposals were brought to the attention of the Commissioners. In short, the ineffectiveness of the Commission has stemmed not so much from the way it made its decisions as from the decisions it made.

Common Regulatory Problems

A number of the CPSC's problems are common to other regulatory agencies. Since its inception, woefully inadequate funding has seriously hampered the effectiveness of the Commission. In fact, the level of funding has consistently been only two-thirds of that authorized by Congress (Table 2). The first year budget request of $30.9 million by the Office of Management and Budget (OMB) was fully $24 million less than what CPSC sponsors considered the absolute minimum needed. The budget reduction in the second year (FY 1975) was the largest inflicted on any federal agency and forced the CPSC to drastically reduce its second-year operating plan. OMB budget requests for the Commission increased only negligibly over the next three years, less in fact than the rate of inflation—a situation which Representative Moss characterized as "deregulation through budget slashing."[12]

Table 2

FUNDING OF THE CPSC

Fiscal Year	Amount Authorized	CPSC Request (in millions of dollars)	OMB Request	Amount Appropriated*
1974	59.0	30.9	30.9	34.8**
1975	64.0	42.8	42.8	37.0***
1976	51.0	49.2†	36.6	39.6
Transition quarter	14.0	12.9	9.1	10.0
1977	60.0	64.9††	37.0	39.8
1978	68.0	41.1	40.2	39.1

* Indicates amount actually available to the Commission.
** $3.9 million transferred from the Food and Drug Administration 1974 appropriation.
*** The original $38.3 million appropriation was vetoed by President Nixon.
† CPSC request later modified to $50.4 million.
†† CPSC request later modified at urging of OMB to $41.1 million.

Seriously compounding the fiscal problem has been a lack of organization and efficiency (see Box). As portrayed in a recent management survey, the working atmosphere in the agency has been "confusing, frustrating, counterproductive, and inefficient."[13] Until recently, CPSC functional units considered rulemaking proposals sequentially: only after all units had *in turn* analyzed and commented on a proposal would the proposal appear before the Commissioners for final decision. This organizational procedure, finally modified in a 1977 reorganization, contributed to much of the delay that has plagued the CPSC's rulemaking efforts in its first five years.

The Pitfalls of Innovation

These obstacles have, to some extent, bedeviled most federal agencies. It is therefore not surprising that many observers of the Commission identify them as the underlying causes of the agency's malaise. Much less attention has been directed to those sources of the CPSC's failures which stem from its experimental nature as a hazard manager and as a new kind of regulator. Two of CPSC's major shortcomings are the result of the attempt to regulate a broad universe of diverse hazards within the catchall framework of consumer products. These two are: the failure to allocate resources effectively and the inability to manage chronic hazards.

Setting Priorities

The misallocation of resources has been largely a result of the agency's inability to establish priorities. As manager of an enormously varied hazard domain, the newly formed agency immediately confronted the difficult question of where and how to begin. Neither Congress nor existing federal agencies provided much guidance.

Until recently, the typical federal regulator was required to act only within a limited range of authority to achieve narrowly circumscribed hazard management objectives. Federal health and safety laws tended to focus on a particular industry (railroads, meat processors), a particular type of product (drugs, cosmetics), or a particular kind of hazard (children swallowing poison or becoming trapped in abandoned refrigerators). During the past decade, however, federal regulation has expanded into much broader arenas: *all* sources of air and water pollution, *all* hazards in the workplace or household, *all* toxic substances. Such broad-scale intervention requires careful analysis of the hazards to be regulated.

INEFFICIENCY AT THE CPSC

In 1975 Congressional investigators discovered that many samples of products sent to CPSC headquarters were lost or mislaid for months.

A ban on aerosol products containing vinyl chloride was overturned by court order because the CPSC failed to prepare an environmental impact statement covering the ban. Former Chairman Simpson later admitted that the need for an impact statement had never occurred to him.

The ban on TRIS in children's sleepwear was overturned by court order because the CPSC failed to allow adequate industry input into the decision-making process.

A certain type of spray adhesive was banned on the basis of a study linking exposure to the adhesive to birth defects. The ban was later lifted when the study's claims proved unsupportable—but only after several women who had been exposed to the adhesive had obtained abortions after hearing of the ban.

Failure to invite public comment on its bicycle standard made it necessary for the CPSC to repeat its rulemaking proceedings before the standard could be issued.

Former Chairman John Byington ordered the preparation of "Product Profiles" soon after taking office. Preparation of these profiles cost $500,000 yet proved to be of so little value that the project was discontinued.

In 1975 the Commission warned that a type of large aluminum kite presented an electrocution hazard and brought complaints against five manufacturers of the product. After obtaining agreements from four of the companies to discontinue making the [illegible] Commission decided the product was actually a toy and should have been outlawed under a different law. The earlier agreements were rescinded and no new ban has yet been issued.

A statement of policy soon after the Commission's inception suggests a considered approach to the problem of priorities:

> The Commission will deal first with those products which pose the greatest risk of injury to the public. The Commission will set (and will periodically reevaluate) its priorities, taking into consideration the number of injuries associated with a particular product, the severity of those injuries, the consumer's likelihood of exposure to that product, and any other factors which the Commission considers important.[14]

Despite this declaration of intent and despite the availability of an effective hazard identification system (see Figure 1), the Commission failed to establish priorities until well into its fourth year. As a result, it became mired in unproductive work, allocating its limited resources haphazardly among both serious and trivial hazards. Chairman Simpson ruefully acknowledged to Congress in 1976 that "last year we estimated 75 percent or more of our activities were reactive as opposed to planned."[15]

It was not until mid-1976 that a priority policy listing criteria for ranking product hazards finally emerged. The criteria employed and the weightings attached by the staff (Table 3) suggest the difficult judgments and the enormous information burden confronting any agency charged with managing such a broad hazard universe. Table 4 shows the annual injuries, possible injury reduction, and 1978 projected goals for each of the 29 high priority hazards finally recognized by the Commissioners.

These data, when compared with the results of CPSC regulations enacted as of January 1, 1978 (Table 1), suggest the extent to which misplaced effort is possible in the absence of clear priorities. While two of the agency's safety rules (for architectural glass and bicycles) should forestall an estimated 200 to 300 thousand injuries a year, the other rules all have much lower injury-reducing potentials. Had the Commission focused its limited resources on higher priority hazards first, it could have provided much greater protection for the American consumer. For example, the Commission estimates that a safety standard for power lawn mowers could save up to 88,000 annual injuries; for bathtubs and showers, 88,000; for public playground equipment, 46,000; for upholstered furniture

Table 3

CPSC PRIORITY CRITERIA

Criterion	Priority Weight*
Frequency of injury	24
Severity of injury	25
Chronic illness and prospect of future injuries	16
Unforeseen nature of the risk	14
Vulnerability of population at risk	9
Probability of exposure to the hazard	12

* Priority weights were arrived at through a staff process at the CPSC. Larger weights indicate assignment of greater importance by the CPSC staff.

Table 4

THE HIGH PRIORITY HAZARDS OF THE CPSC

EPS Priority	Product	Annual Injuries (in thousands)	Anticipated Annual Injury Reduction (in thousands)	1978 Proposed Goals
1	Asbestos	N.A.	N.A.	Preparation of Final Ban of Additional Products Containing Asbestos
2	Lawn Mowers	100.0	50-88	Final Standard Completed. Begin Development of Proposed Certification Rule
3	Gas Space Heaters	4.8	1-1.2	Publish a Proposed Ban for Unvented Gas Space Heaters
4	Communication Antennas	0.4	N.A.	Completion of 75 percent of Sec. 7 Rule Feasibility Study. Complete Enforcement Plan for Labeling Standard
5	Public Playground Equipment	228.0	11.6-46.7	Publish Proposed Technical Requirements for Regulation
6	Chlorofluorocarbons in Aerosols	N.A.	N.A.	Proposed Regulation of Uses of CFC's Other Than Non-Essential Aerosol Propellants is Published. Economic Impact to Be Studied
7	Architectural Glazing	484.0	325.4	Promulgate Final Certification Reg.; Prepare a Weathering Amendment
8	Unstable Refuse Bins	28.4	17	Issue and Enforce Ban on Unstable Refuse Bins
9	Lead in Paint	N.A.	N.A.	Issue and Enforce Final Banning Regulation for Paint Containing .06 Percent Lead
10	Baby Pacifiers	N.A.	N.A.	Effective Date of Banning Reg. is 2/26/78
11	Sharp Points & Edges on Toys	44.7	7.2-20.9	Publish Final Technical Requirements on Sharp Points
12	Methyl Alcohol	N.A.	N.A.	Issue Final Regulation
13	Upholstered Furniture	88.1	31.4-44.0	Remedial Options Analyzed to Determine Strategy. Take Appropriate Action
14	[illegible]			Issue Final Regulation on Metal & Glass Edges in Toys
15	Children's Sleepwear	N.A.	N.A.	Publish Sleepwear Enforcement Policy
16	Miniature Christmas Tree Lights	1.9	0.8-1.4	Issue Final Mandatory Safety Standard
17	Television Sets & Stands	51.6	20.6-25.0	Participate in Appropriate Standard
18	Aluminum Wire	N.A.	N.A.	Section 15 Activities Continue on Old Technology. A Voluntary Standard Will Be Considered for New Technology
19	Ranges & Ovens	60.6	17.6-20.8	Support and Evaluate Efforts of Voluntary Stnd. Groups (UL, ANSI)
20	Skateboards	80.0	N.A.	After Remedial Options Analysis Is Completed (1977) Decision on Further Action
21	Extension Cords & Trouble Lights	8.7 (cords) N.A. (lights)	0.4-0.7 (cords) N.A. (lights)	Through Offeror Process, Publish Proposed Mandatory Safety Standard
22	Bicycles	1,170.0	217.8-270.5	Amend Reg. to Include Wet Brake and Pedal Slip Criteria
23	Matches	24.0	4.8-7.2	Implement Stnd. May 1978
24	Ladders	165.0	20.0-85.1	Support and Monitor ANSI Work on Revised Voluntary Standard for Metal Ladders and for Draft Voluntary Standard on Wood Ladders
25	Energy Conservation	N.A.	N.A.	Hazard Analysis Completed. Initiate or Participate in Appropriate Standards Activities
26	Bathtubs & Showers	180.1	38.8-87.5	Support and Participate in Completion of Voluntary Stnd.
27	Smoke Detectors	6.1	N.A.	Decide on Feasibility of Sec. 7 & Remedial Strategy Research Complete. Take Appropriate Action
28	Children's Football Helmets	131.6	N.A.	Remedial Options Complete. Option Pursued as Selected by Commission
29	Small Parts in Toys	7.0	4.2-4	Publish Proposed Regulation
Total (for Products with Injury Estimates)		2,809.3	770.3-1,026.1	

(a flammability standard), 45,000. Instead, the agency chose to develop standards for such products as matchbooks, fireworks, pacifiers, and swimming pool slides, each of which will likely forestall no more than 10,000 annual injuries. In short, the lack of clear priorities has made the CPSC an erratic hazard manager.

Chronic Hazards

During the first five years of its existence, the CPSC concentrated its managerial effort on acute hazards. For FY 1978, for example, the Commission allocated only thirteen percent of its budgetary resources to chronic hazards (Figure 2) despite the growing contribution of these hazards to overall mortality in the United States and the greater costs involved in their evaluation and control. Also, until very recently, the Commission has had no policy or procedure to guide its response when evidence of such hazards came to its attention.

Further, as noted above, the Commission's major hazard identification program (the hospital emergency room reporting system) is oriented to acute hazards. Its chronic hazard identification system consists of a computer system which draws on several nationally available listings of hazardous materials (MEDLINE, TOXLINE, CHEMLINE and the Clearinghouse on Mutagens and Carcinogens). A recent review by the National Research Council found, however, that these data bases omitted information on many chemicals present in household products and that the CPSC suffered a serious lack of high level technical expertise: epidemiologists, biostatisticians, toxicologists, and medical scientists.[16] It is not surprising, therefore, that by the beginning of this year the Commission had regulated or proposed to regulate only six substances (spray adhesives, vinyl chloride, lead-based paint, asbestos in patching compounds and fireplace logs, TRIS-treated sleepwear, and chlorofluorocarbons) posing long-term health risks, and in only one of these actions did the initiative come from the Commission itself.

The tendency to date has been to attribute the Commission's impotence in

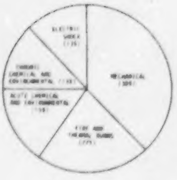
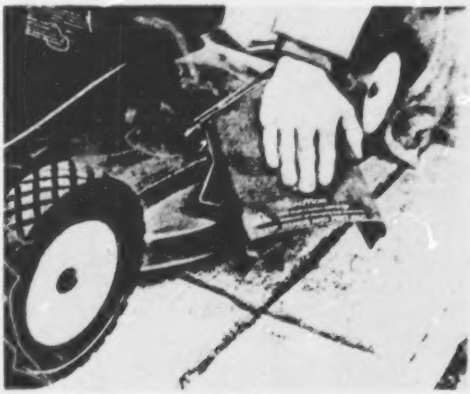


FIGURE 2. CPSC budget allocations among programs for fiscal year 1978. Note that acute hazards (electric shock, mechanical accidents, fire and thermal burns, and chemical and environmental risks) take up 87 percent of the budget, leaving only 13 percent for chronic hazard management. The total budget for 1978 was $39.2 million.

chronic hazard control largely to administrative mismanagement. While some of the criticism is undoubtedly well placed, it obscures the much more fundamental problems this class of hazards presents to a single small government agency. Given that the cause of seventy to eighty percent of all cancer is scientifically unexplained, that the assignment of specific carcinogens to specific cancers is the exception, and that the causes of heart disease are still poorly charted, regulating long-term hazards, even with plentiful resources, is bound to be an enormously difficult task.

Complicating the job of the CPSC is the fact that consumer products are formulated from existing stocks of chemicals well along in the productive process. It is therefore questionable whether even improved management and augmented resources will permit satisfactory control of chronic hazards and whether the CPSC should be in this business at all. Although the Commission has recently formulated a chronic hazards policy,[17] there is a strong argument that such hazards either should be the responsibility of some coordinated intergovernmental program (as suggested by the current activities of the Interagency Regulatory Liaison Group and the Toxic Substances Strategy Committee) or that the legislative mandate of the CPSC should be revised to vest all chronic hazard control in some umbrella agency (a Toxic Substances Commission?) which could deal with these hazards on a much more comprehensive

The power mower standard was the sole CPSC standard developed by a consumer organization.



basis. This would free the CPSC to do what it does best—manage the acute hazards associated with consumer products.

A Frustrated Attempt

In creating the CPSC its Congressional sponsors sought to establish a model of regulatory reform. They included in the Consumer Product Safety Act innovative provisions designed both to insulate the agency from outside political pressure and to make it open, accessible, and responsive to the public. After more than five years the CPSC has fulfilled neither expectation.

A number of "insulating provisions" are included in the act. The agency's five Commissioners do not serve at the pleasure of the President; rather, once appointed by the President to staggered seven-year terms, they continue in office unless removed for neglect of duty or malfeasance. No more than three of the five Commissioners may be from the same political party. The hiring of new personnel, other than Commissioners, is not subject to White House review or approval.[18] The CPSC submits its budget requests and legislative proposals simultaneously to the Congress and the President's Office of Management and Budget. This innovation marked the first time a federal agency was not required to submit its proposals to the OMB for review and modification *prior* to submission to Congress, the intent being to reduce the CPSC's dependence on White House fiscal decisions. The act also forbids policy making CPSC employees from taking jobs with industries within CPSC jurisdiction for at least one year after leaving the agency, a provision recently favored by President Carter to slow the "revolving door" between regulators and regulated industries. The Commission is also required to include in its annual report a log of all meetings between Commission officials and persons affected by its regulatory activities.

Despite these insulating safeguards, in the past, White House interference in the affairs of the CPSC has been pervasive. President Nixon did not fill the five Commissioner positions until five months after the creation of the agency. Most of the Commissioners finally selected, including Chairman Simpson, a Republican businessman, shared Nixon's distaste for the federal regulation of private industry. While Nixon searched for Commissioners his Office of Management and Budget (which had advised Nixon to veto the Act) almost singlehandedly set up the CPSC's organizational structure, and arranged the wholesale transfer of 530 personnel from other agencies to fill most of the 768 original CPSC positions.[19] Despite the innovative budget submission requirement, the OMB also dominated the agency's funding process. Congressional appropriations committees, unaccustomed to receiving budget requests directly from an agency rather than through the OMB, paid greater deference to the latter's recommendations. The debilitating budget appro-

Woodburning
Set

priations detailed in Table 2 were the result. Substantial third- and fourth-year funding increases, confidently anticipated by CPSC planners, were never forthcoming.

In sum, the effort to establish the CPSC as a politically independent hazard manager within the federal government was a failure, a fact that attests both to the power of the executive branch to assert its authority over administrative agencies and to the inadequacy of the provisions in the act designed to counter that authority. In addition, Congress itself is a potential source of political pressure on the agency whenever affected industries lobby to have bans or standards modified or set aside.[30]

Public Participation

Many would agree that the CPSC has become one of Washington's most accessible and open agencies but fail to link the shortcomings of the CPSC as hazard manager to the CPSC as a stimulator of public participation. It is assumed that, in a well-ordered world, these two roles must be somehow compatible, indeed reinforcing.

The CPSC's "offeror" process requires the Commission to accept the offer of one or more qualified persons or groups to develop a needed safety standard. The intent was that both industry and consumer groups would become directly involved in the Commission's most important rulemaking function—the issuance of product safety standards. To date, however, industry has almost totally dominated the process. Only one standard (for power mowers) has been developed by a consumer group (Consumers Union) and one other (for miniature Christmans tree lights) by a joint industry-consumer group offeror.

In retrospect, it is also apparent that the act's congressional sponsors sorely underestimated the time and money needed to draft comprehensive safety standards. Some offerors, and others participating in the process, have spent millions of dollars, and four to five years, working to draft acceptable standards. Consumers Union found its four-year involvement with the power mower standard so costly that it stated in a letter to the Commission that it would probably never again serve as an offeror.[21] Although consumer representatives must, by law, be added to all standard development committees, they usually lack the technical expertise and funding to contend effectively with well-heeled industry groups. The Commission, for its part, has failed to provide the resources needed for effective consumer participation—though it clearly has the power to do so.[22]

The other measure intended to assure public involvement in CPSC rulemaking—the citizen petition process—presents the agency with the dilemma of how to reconcile the need for effective citizen participation with the need for efficient hazard management. Recently the CPSC has moved toward a policy of summarily denying petitions not related to its high priority hazards. Such a policy not only potentially weakens the "regulatory reform" portion of the CPSC experiment but also may undermine the greatest substantive virtue of the petition process—its ability to alert the Commission to the occasional hazard that is unidentified or underestimated by normal agency processes.

An even larger issue, however, is involved in determining the long-term effectiveness of the CPSC. Facing a regulatory domain occupied by powerful industry groups, the Commission

CHANGING PRIORITIES AT THE CPSC

Since she became chairman of the CPSC in July, Susan Bennett King has moved to bring about substantial changes in the agency's approach to hazard management. In a recent interview in the Boston Sunday Globe, King stated that the Commission must reduce the number of items on its priority list and must concentrate especially on the "unseen hazards" from which consumers are least able to protect themselves. Such hazards would include aluminum wiring and cellulose home insulation (the Commission is presently seeking a court decree that will allow it to take action against the use of aluminum wiring as an "imminent hazard" and on September 8 the Commission issued a mandatory safety standard for home cellulose insulation). On the other hand, King wants the on-going study of ladders dropped since 80 percent of the problems are the result of consumer misuse rather than of defects in the product. The Commission's focus, King holds, should be on those hazards or risks which are not readily foreseeable by the public. King regards this emphasis on serious unseen hazards as the "key to survival" for the agency.

In order to increase the efficiency of the Commission, King advocates greater use of "conditional bans" to control unsafe products. Conditional bans would provide a method for eliminating the unsafe aspects of products while avoiding the time-consuming, cumbersome process entailed in drawing up mandatory standards. As one of the most serious obstacles she faces, King cites the problem of diverting more of the agency's $40 million annual budget to new programs that fit the new priorities. Changing program priorities is difficult, she says, because of ceilings on hiring and the rigidities of the Civil Service system.

King, whose appointment was supported by most consumer groups, knows that the future of the CPSC is in her hands. Wendell Ford (D-Ky.), who heads the Senate subcommittee that has the oversight responsibility for the CPSC and who has been highly critical of the Commission in the past, led a successful fight to extend the life of the Commission for another three years—in large part because he believed that Susan King could turn the agency around. However, Ford has also said: "If this agency fails to live up to the expectations we have for it, I'll be the first to dismantle it when the reauthorization comes up again." Susan King and her fellow Commissioners have less than three years to demonstrate to Congress that the CPSC has a job worth doing and that it has the will and ability to do it well.

depends for its success on the existence of an informed and active consumer constituency. But after displaying an unprecedented degree of cohesiveness in the late 1960s and early 1970s, the consumer movement is now dispersed and disorganized, its political clout noticeably diminished. Though consumer groups have the support of the chairmen of the primary CPSC oversight committees in Congress (Wendell Ford in the Senate and John Moss in the House), support for the Commission on Capitol Hill appears to be dwindling. Congressional approval of John Byington as CPSC Chairman in 1976 over the opposition of almost every major consumer group underscored the weakness of both the agency and its consumer constituency.

It is possible that the consumer movement may fall victim to the nation's overriding concern with inflation. A recent Harris poll on consumerism, for example, reveals a public which desires increased protection from "dangerous consumer products" but is also greatly concerned about the high prices of consumer goods and hostile to increased government regulation.[23] The need for an informed and involved constituency is one that is apparently recognized by the new CPSC Chairman, Susan Bennett King, who in a recent interview stated that one of the most important things the Commission has to do is to tell its own story better.[24]

The Problem

During the five and a half years the CPSC has been in existence, it has been unaggressive and ineffective in meeting its responsibilities to inform and protect the American consumer. It has consistently backed away from forceful regulation, devoted itself to trivial as well as serious hazards, and repeatedly opted for less aggressive actions than its staff has recommended. It has failed to provide consumers with comparative safety information for products so that individuals can use their own purchases to create safer home environments. Finally, the Commission has to date failed to develop the technical or fiscal resources to control the chronic hazards presented by consumer products, despite the fact that such hazards account for an increasing proportion of mortality in the United States and are the subject of growing public concern.

It is apparent that the Commission shares many problems with other regulatory agencies—legislative inadequacies, serious underfunding, executive interference, a conflict of interest problem in the expert advice it receives, and powerful industry resistance. But the Commission has exacerbated these with a number of problems distinctively its own—a degree of administrative mismanagement and disorganization spectacular even in the context of large bureaucracy, ineptitude in its rulemaking process, responsibility for a vast and varied hazard domain, failure to set clear priorities for Commission efforts, and lack of any real capacity to manage chronic hazards.

Some Suggested Solutions

To improve the CPSC, we would recommend the following four specific changes:

- Congress should reconsider the appropriateness of the Commission's domain of hazard responsibility. It should either remove the Commission's responsibility for chronic hazards and vest it in a new central governmental institution or, alternatively, mandate uniform national chronic hazards policies and procedures which would apply to all federal regulatory agencies.
- Congress should provide more guidance on the criteria for setting priorities and should specifically indicate how the Commission's resources should be allocated in relation to those priorities. Congress should also specify milestones for demonstrated achievement in creating a safer environment in and about American households.
- The Commission should immediately undertake an ambitious program, adequately funded and staffed, to determine the relative safety of various products within different classes of products. It should then mount a vigorous campaign to inform the public so that this information can be used by consumers in making decisions about their purchases.
- The Commission should take effective action to counter those political influences in its regulatory process which are clearly inimical to the protection of the American public from the [illegible] of consumer products. Specifically, the offeror process should be revamped to reduce industry dominance, substantially increased funding should be provided to support enlarged consumer participation in the agency, and the creation of a full time "consumer advocate" within the agency should be reconsidered.

ANY CITIZEN CAN . . .

Petition the CPSC to issue, amend, or revoke a consumer product safety rule. The petition can be a handwritten letter. It must be granted or denied within 120 days. Petitioners can appeal a denial of a petition in the courts.

Provide the Commission with information about product-related injuries or offer recommendations about unsafe products.

Comment in writing or orally on any proposed standard once it is published.

Request judicial review of a mandatory safety standard within sixty days of the time it is issued.

The Larger Lessons

An examination of the difficulties which have plagued the CPSC experiment suggests that there are lessons to be learned that have implications which extend far beyond the agency itself. For example, it seems likely that the trend toward more ambitious federal efforts to control the hazards of technology will mean that government agencies will increasingly be confronted with the management of broad and varied hazard domains. The CPSC experiment indicates that there is a pressing need for the classification of hazards (hazard taxonomies) and for a defensible assignment of priorities. Ad-hoc, case-by-case response is the quicksand of modern hazard management.

A second lesson can be learned from the CPSC's mixed record as an experiment in regulatory reform. The experiment indicates how little is known about how to give the public an effective voice in bureaucratic decisions—and suggests that even less is known about how to design innovations that contribute to rather than detract from the substantive work of an agency.

Finally, given the fact that some benefits to society must usually be foregone in order to reduce hazards, a regulatory agency can travel down the road of hazard control only so far without a "safety constituency." Long-term success in creating safer households, workplaces, or other environments depends upon an unambiguous public resolve both to demand protection and to pay the price, together with a Congressional commitment to implement change even in the face of troubled economy.

The first testing of swimming pool slides by the CPSC, June 1975.

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All pictures for this article were provided by the Consumer Products Safety Commission.

NOTES

1. As quoted in Jo Thomas, "Performance of Consumer Agency Disappoints Its Early Supporters," New York Times, January 30, 1978.

2. U.S. House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, Federal Regulation and Regulatory Reform, 94th Congress, 2nd Session, Washington, 1976, p. 197. The Commission may regulate any product that is used in or around a residence or school for the personal use, comfort, or enjoyment of a consumer. Specifically excluded from CPSC's jurisdiction are motor vehicles, fuels, nuclear materials, pesticides, aircraft, boats, foods and drugs, medical devices, cosmetics, tobacco products, firearms and ammunition, all of which are regulated to some degree by other federal agencies.

3. For a comprehensive breakdown of the CPSC's legal authority see "The CPSC: An Agency Manual," George Washington Law Review, 43 (May 1975).

4. Almost all successful challenges to the Commission's rules have been based not on the substance of the rules but on failure of the Commission to follow proper rulemaking procedures.

5. Section 7 (d) of the Consumer Product Safety Act.

6. Section 10 (e) of the Consumer Product Safety Act.

7. See Federal Regulation and Regulatory Reform referred to in note 3 above, p. 195.

8. This claim should be viewed in light of the fact that some 2.5 million firms sell 10,000 consumer products annually. Only 350 notifications may indicate the failure of some firms to report such hazards. Ibid., p. 211.

9. Aqua Slide 'n' Dive Corporation v. CPSC, _f. 2d._ (5th Cir., March 3, 1978).

10. Testimony of Chairman William Simpson, U.S. House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, Hearings on Regulatory Reform, 94th Congress, 2nd Session, IV (1976), pp. 12-14, 27, 91.

11. A report commissioned by President Nixon in 1971 (known as the "Asch Report"), for example, thoroughly criticized collegial decision making. Former CPSC Chairman Simpson has also criticized decision-by-commission. In a response to questions submitted by Representative John E. Moss, Simpson referred to collegial decision-making as "an unworkable alternative for effective and productive leadership of an organization."

12. See Hearings referred to in note 11 above, pp. 1-2.

13. Decision Studies Group of Washington, D.C., conducted the survey. See The New York Times, January 30, 1978.

14. U.S. House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Commerce and Finance, Hearings on Consumer Product Safety Commission Oversight, 93rd Congress, 2nd session (1974), p. 88.

15. See note 11 above, p. 15.

16. See National Research Council, Assembly of Life Sciences, Committee on Toxicology, a Review of the Role of Health Sciences in the Consumer Product Safety Commission (Washington, D. C.: The Council, 1977).

17. The first "phase" of the CPSC's chronic hazards policy—the classification of potentially dangerous household chemicals—has recently been challenged in the court on procedural grounds by Dow Chemical Co.

18. This 1976 Amendment to the Act grew out of a dispute between the CPSC and the Civil Service Commission resulting from the CPSC's refusal to approve the hiring of CPSC employees who had not received political clearance from the White House. This amendment clarified CPSC's authority to by-pass the White House when hiring new personnel.

19. While the sponsors of the CPSA envisioned the transfer of some personnel, they hardly contemplated that 70 percent of the CPSC's original manpower would be from ongoing government programs. This influx of employees, who had operated under the policies and practices of their former organizations, contributed significantly to the CPSC's start-up problems.

20. According to Rhoda H. Karpatkin, Executive Director of Consumers Union, the lawnmower industry has lobbied Congress extensively regarding power mower standards.

21. Letter from Rhoda H. Karpatkin to Sadye Dunn, Secretary of the CPSC, dated January 9, 1976, reprinted in Note 14 above, p. 364. As a result of this letter, the Commission reimbursed Consumers Union for most of its out-of-pocket expenses. The CPSC in 1978 is in its fifth year of work on power-mower safety standards, and has already spent over 11,000 person-hours, $800,000 of CPSC resources, and $166,000 provided to Consumers Union. The $1.2 billion lawnmower industry, for its part, estimates that it has spent $4 million in research and response. Meanwhile, Combined Insurance Co. of America projects some 165,000 injuries and several deaths this year from power mowers. Hartford Courant, May 24, 1978.

22. See Note 8 above, p. 221. The Commission now has before it a rulemaking petition seeking a regulation providing for funding of consumer participants.

23. See Tables III-1 and VI-9, Louis Harris and Associates, Inc. and Marketing Science Institute, Consumerism at the Crossroads (N.P.: 1977), pp. 29 and 69 respectively. Rhoda Karpatkin of Consumers Union comments that she believes there is increasing public demand for product safety and consumer protection and considers the results of the Harris poll "heartening" and an indication of the dual desire for better, safer products and an end to inflation.

24. Boston Sunday Globe, September 24, 1978.

FEDERAL REGULATION

Too Little: The Consumer Product Safety Commission and Asbestos

by Howie Kurtz

Last winter, in living rooms across the country, more than a million people warmed themselves in front of fires fed by artificial fireplace logs. Most of them did not realize that these artificial logs and ashes were emanating small particles of asbestos that floated slowly through the air and into their lungs, where the deadly fibers became permanently embedded.

When asbestos fibers are absorbed into the lungs, they cause a fatal disease that scientists first diagnosed in the late 1920s. They found that many asbestos workers were dying from a disease they called asbestosis. Tiny asbestos fibers accumulated in their lungs and were soon covered by scar tissue that made breathing increasingly difficult. The scar tissue would thicken, even after the workers were no longer being exposed to asbestos, and the strain on their pulmonary systems became so great that they often died of heart failure before their lungs could give out.

The growing asbestos industry, however, chose not to heed the alarming studies that were published in this country beginning in 1930. By 1935, asbestos was found to cause lung cancer, and later it was linked to cancer of the stomach, intestine, and rectum. Asbestos was also found to cause mesothelioma, a particularly painful form of cancer that eats away at the lining of the lung or abdominal cavity and generally kills its victims within one year after its first symptoms appear. Because the asbestos manufacturers deliberately ignored the mounting evidence, at least 400,000 workers—or four out of ten in the industry—are now expected to die from asbestos diseases. It was not until the early 1970s that strict limits on the amount of asbestos to which workers could be exposed were imposed on the industry by federal law.

And today, millions of American consumers are unwittingly being exposed to this same deadly asbestos. Those artificial fireplace logs and ashes are just one of the more than 3,000 consumer products that, although most of the public doesn't know it, contain asbestos.

Such hidden dangers in the marketplace are the reason that Congress decided five years ago to create the

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Howie Kurtz is an investigative reporter for columnist Jack Anderson.

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Consumer Product Safety Commission. But the commission, which is supposed to ban products that injure or kill people, has not acted against this hazard with any greater sense of urgency than federal officials displayed when workplace hazards were exposed in the 1930s.

The commission has been such an abysmal failure that it is at least as responsible as any other government agency for the plummeting popularity of consumer protection. It's no secret that people have become increasingly fed up with meddlesome government bureaucrats issuing annoying minor regulations on such matters as interlocking seat belts and child-proof aspirin bottles. But even the consumer protection movement's most ardent critics would have to concede that the government has a basic responsibility to stop companies from foisting dangerous products on an unsuspecting public. Asbestos, after all, is no borderline case about which reasonable people can disagree, and the most conscientious citizen has little way of knowing of the hidden ingredient in artifical fireplace logs and ashes.

Instead of cracking down on dangers like asbestos, however, the CPSC has been so ineffective that even its most enthusiastic supporters have become disillusioned. Since its inception it has issued safety standards for only one product, swimming pool slides, and even that too , two years. The commission is so stricken with bureaucratic paralysis that it has not acted on a backlog of over 150 questionable products.

The CPSC was first asked to ban artificial fireplace logs and ashes that contain free-floating asbestos in November 1975, in a petition from environmental writer Rachel Scott. In July 1976, the Natural Resources Defense Council, an environmental group, asked the commission to ban asbestos patching compounds, which are widely used to repair crumbling ceilings, walls, and floors. "Even very brief exposure to asbestos fibers such as those experienced by consumers of patching compounds have been shown to substantially increase the risk of cancer," the group warned.

The commission's own scientists readily agreed. The following month, Robert Hehir, director of CPSC's Bureau of Biomedical Science, warned in a memo: "Data demonstrating the adverse effects of asbestos in humans, as well as in experimental animal studies, is clear and irrefutable .... Exposure to consumer products containing [free-floating asbestos] poses an unnecessary, unreasonable and completely avoidable potential risk to consumers that cannot be adequately controlled by warning labeling."

Despite this unequivocal warning, the commission did absolutely nothing for another year. One possible reason for the delay is suggested in another internal memo: "The longer it takes to promulgate a ban and/or repurchase [of asbestos], the smaller the economic effect on the industry will be." Most of the commissioners are Republicans appointed during the Nixon-Ford years, and they often appear concerned more about the impact of their actions on corporate profits than their effect on public health. Several of them have voted to ban products only reluctantly and under the greatest public pressure.

"They laughed at our first petition," recalls Barry Castleman, the National Resources Defense Council lawyer who wrote it. "It made the case for them, but they spent a year quibbling with us. They had no sense of the consequences." One CPSC staff member agrees: "We dragged our feet interminably. The staff still hasn't looked at many products that contain asbestos. Nobody told us it was a high priority."

Finally, the commission voted last April to ban patching compounds and fireplace logs and ashes that contain asbestos. But although two million people a year are being exposed to these products, the CPSC didn't order an immediate halt to sales and a recall of existing inventories. Instead, it is allowing sales to continue while it draws up regulations banning future use. This has been dragging on for months and may not be completed for months more. "What this means," complains Castleman, "is that stores can have special sales on asbestos patching compounds, and a few more people will get cancer."

The CPSC's voluble chairman, S. John Byington, concedes that his agency wasn't as aggressive as it might have been. "Oh sure, we could have moved faster," he says. But Byington claims he never received the scientific memo that detailed the risks of asbestos. "What happened after it was written, God only knows," he says. "We never saw that memo." Nevertheless, it has been known since a landmark study in 1964 by Dr. Irving Selikoff of New York's Mt. Sinai School of Medicine, the country's leading asbestos researcher, showed that people can get lung disease from brief exposure to free-floating asbestos fibers that break free from finished products.

'Cosmetic Changes'

Byington, a handsome young Republican from Grand Rapids, Michigan, who was appointed last year by President Ford, believes the commission's shortcomings can be corrected through better management techniques. He insists that he will cope more effectively with CPSC's massive backlog of health and safety hazards now that he has reorganized the agency's structure. To the second highest paid agency staff in Washington--about 200 of its 900 employees earn over $28,000–he has added five "supergrade" managers, who report directly to him. But one CPSC member, R. David Pittle, told Byington in a private memo: "Except for a few cosmetic changes, you have not really reorganized the agency at all. You have simply added a layer of unneeded supergrade Associate Executive Directors over the technical bureaus."

While Byington has been fiddling with organizational charts, his commission has done very little research on other dangerous asbestos products. For example, asbestos remains a hidden ingredient in such innocuous products as children's modeling clay and papier mache. Dr. Selikoff discovered last year that thousands of pounds of modeling clay ordered by New York schools contained as much as 50 per cent asbestos. Asbestos is not a necessary component of these products, but manufacturers prefer it because it is much cheaper than its substitutes.

Hundreds of thousands of tons of asbestos also are used in textured paints, cement powders, brake linings, stove panels, wallboards, and floor tiles. Manufacturers are now rushing to obtain patents for dozens of new uses for asbestos, apparently secure in the knowledge that the CPSC is unlikely to act against them soon.

Byington, meanwhile, has been far more energetic in pursuing his own career than dangerous products. The talkative chairman, who is said to have political aspirations in Michigan, flew at taxpayer expense to Hong Kong, Taiwan, Tokyo, Brussels, Geneva, Bonn, Hamburg, Puerto Rico, and the Virgin Islands during his first ten months in office. Byington's avowed mission–explaining U.S. safety standards to foreign officials–could have been accomplished just as well by long-distance phone calls. But as one CPSC official puts it, "John likes the spotlight, the travel, the glorification."

Another example of Byington's passion for public relations over product safety is the $425,000 he paid an Atlanta advertising firm last year to promote the commission's work–a strategy that, naturally, entailed more traveling and speeches for its chairman. He also spent $45,000 to make television commercials featuring a character named "Safety Sadie," who offers friendly tips on matters like fireworks and bicycles. Then he decided he didn't like the actress who played Sadie, threw the commercials in the trash can, and led the search for a new Sadie, eventually settling on the wife of comedian Dom DeLuise.

'Meaningless Mush'

Such incidents have demoralized many of the commission's workers; one survey shows that 43 per cent of them don't think their agency is doing a good job. They were further aggravated by Byington's expenditure of $500,000 on product profiles that turned out to be worthless. An angry letter from CPSC employees to Senator Wendell Ford, one of Byington's harshest critics, explained: "At the direction of management the profiles were re-written numerous times . . . each time with additional facts and figures incorporated. Finally, senior staffers took the profiles and manipulated them into meaningless mush so that they would be innocuous enough to release under Freedom of Information."

To put it bluntly, the CPSC has failed to reduce deaths and injuries to consumers because Byington and his colleagues have not been aggressive enough in banning the products that cause them. Part of the reason for this is that the commission sees manufacturers, rather than their customers, as its most important constituency. The economic impact on business, Byington admitted, was a factor in his decision not to push for an immediate recall of asbestos products.

The manufacturers of these products have known for years that asbestos can hurt people, just as they knew 50 years ago that they were destroying the lungs of their workers. In the pursuit of profit, the companies have been willing not only to peddle harmful products, but to create a market for them through aggressive and sometimes misleading advertising that glosses over their dangers and defects. They took a calculated risk that the hapless bureaucrats in Washington would not take their products off the market in the near future. So far, that risk has paid off. ■

Issues of the Day –
Product Safety

Howard E. Brehm*

"Industry must include in its research and engineering activities
a thorough and coordinated approach to product safety
so that it receives as much attention as performance, appearance, producibility, and cost."

Five years ago, the Consumer Product Safety Act emerged from Congress. This act established a five member Consumer Product Safety Commission whose objective is to reduce injuries to consumers using consumer products. It defined a consumer product as an article for use by consumers in or around the home, at school or in recreation or otherwise and provided certain remedies for dealing with hazardous products which include such acts as banning the product and seizure of the product.

Additional actions provided for in the act could be voluntary standards and educational programs. These include: establish an information gathering requirement for hazards and accidents and have the authority to inspect company records dealing with complaints, injuries and similar subjects; establish the requirement that all manufacturers, distributors and retailers report to the Commission any product which fails to comply with an applicable consumer product safety rule or which contains a defect which creates a substantial risk of injury to the public; establish inspection and record-keeping requirements and the requirement to make reports as the Commission may deem necessary to demonstrate compliance with the Act; establish that imported products must comply with the Act, but that exported products need not; and establish civil and criminal penalties for violation of the Act.

The Consumer Product Safety Commission

The Consumer Product Safety Commission began operations in 1973 and now has over 800 employees located in two buildings in Washington and thirteen field offices across the United States. They have a budget of about $40 million dollars per year. A variety of internal offices and associate executive directors have been established to cover communications, congressional relations, public participation, strategic planning, hazard identification and analysis, engineering and sciences, and compliance and enforcement, all to carry out the responsibilities established by the Act.

The Consumer Product Safety Commission administers a total of five laws. I have already mentioned the Consumer Product Safety Act. The others are the Flammable Fabrics Act, which deals with the flammability of children's sleepwear, carpeting, and other fabrics; the Federal Hazardous Substances Act, which relates to the control and labeling of household chemicals; the Poison Prevention Packaging Act, which was responsible for the childproof packaging on medicines; and the Refrigerator Safety Act, which limits the force required to open a refrigerator door to a maximum of 15 lbs.

One of the most powerful provisions of the Consumer Product Safety Act is section 15(b) which reads: "Every manufacturer of a consumer product distributed in commerce and every distributor and retailer of such product who obtains information which reasonably supports the conclusion that such product 1) fails to comply with an applicable consumer product safety rule; or 2) contains a de-

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*Director, Corporate Product Safety, Whirlpool Corporation. Article is condensed from paper given at I.R.I. Fall Meeting.

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fect which could create a substantial hazard described in subsection (a) (2), shall immediately inform the commission of such failure to comply or of such defect unless such manufacturer, distributor or retailer has actual knowledge that the commission has been adequately informed of such defect or failure to comply."

In recall situations, products may be returned to the factory for rebuilding, or reworked in the field using prepared repair kits. In either case, the products must be located before the repairs can be accomplished. The location process is extremely difficult and very expensive. It involves many people throughout the country who are attempting to locate product under severe time pressures. The longer the product has been in the field, the more difficult it is to locate. Anyone who has conducted a product recall will attest to the fact that product recalls are upsetting to the organization and expensive to conduct.

Fines under the civil penalties provisions for reporting potential substantial hazards too late can be expensive. Two cases recently have involved fines of one hundred and twenty-five thousand dollars and three hundred and twenty-five thousand dollars for alleged violation of the reporting rule.

Another provision of the Consumer Product Safety Act relates to the preparation of product standards. These may be generated by the voluntary standards system and adopted by the Commission, or they may be developed by offerors under the standards offeror program. They also may be prepared directly by the Commission staff.

Impact on R & D

With this background, let's turn to the impact of the Consumer Product Safety Commission on industrial research and engineering. What does it all mean? What can we do to cope with it? And what will be the results in terms of research and engineering projects, the utilization of time, talent, money and facilities?

First, industry must include in its research and engineering activities a thorough and coordinated approach to product safety so that it receives as much attention as performance, appearance, producibility, and cost. To accomplish this, product safety should be formalized and centralized in the technical division under the guidance of someone whose function is to know, understand, and communicate to his or her associates what is going on in the product safety arena, and provide the means by which research and engineering can adequately develop and control the safety of the product. The motivation for this action is easily found both in the requirements of specific product safety laws and in the common law relating to product liability.

The product safety specialist should be qualified product engineer, familiar with the products and operations of his company and his industry. He must know, and be capable of working with, all levels of responsibility in the company, and he must be willing and able to preach the gospel of product safety both to those who agree with him and support him — and to those who disagree with him and resist him. He is an organizer of the product safety function. He is a communicator, a listener, an evaluator, and a promoter. Above all, he is the focal point of the product safety program.

The effort of this person can quickly reflect on the bottom line of the operating statement, as he eliminates product safety problems in products both before they leave the factory and after they move into the field. His efforts can also reflect positively on the company image as its concern for the customer and for the safety of its products become apparent.

To put teeth into any company product safety program, the product safety specialist must be supported by a policy detailing the company's product safety posture and his responsibilities. The policy and the responsibilities must be communicated throughout the company by top management so there is both understanding and acceptance of what the product safety specialist is doing.

The burden of product safety has landed squarely on the technical function, because it is engineers, whether research, design, production, or quality control, who create and manufacture the products, and who, therefore, are the people with the training, experience and opportunity to directly influence product safety. True, there are countervailing forces to be considered. Inherent product limitations, market requirements, government regulations, and the like make the task of building safer products more challenging and difficult, but no less essential.

Technical Considerations

Now, what are some of the major technical considerations in designing and producing safer products? The most important item is knowing the product — what it will do, and what it will not do, under various conditions of normal use, misuse, and abuse.

There are a number of tools which can be used in evaluating a product for potential hazards. Some of these are gross hazards analysis, classification of hazards, frequency severity analysis, failure mode and effects analysis, hazard criticality ranking fault tree analysis, energy transfer analysis, catastrophe analysis, human error analysis, transportation hazard analysis, and maintenance hazard analysis. The purpose of most of these techniques is self-explanatory, and most are well documented in the literature. They should be employed on a selective basis at various stages in the life of the product from concept to disposal.

The results of all of these evaluations can be combined into an all inclusive evaluation, generally called a product safety audit. Such audits are conducted regularly on an established schedule by the technical department. The product safety audit should be the final look at the total product, and the mechanism which determines final acceptance or rejection prior to release for manufacture.

This audit procedure simply addresses the basic question, will the product perform safely the job for which it was designed? To determine this, the research and engineering departments that have the technical expertise and/or the design control of the product must become involved in a number of ways. Some of these are: 1) Knowing the product — what it will do under situations of use, misuse and abuse, and how it will interact with people, whether they are expert or not in its operation. 2) Investigating how the customer will relate to the product and how owners will use, misuse or abuse the product, and then allowing for such treatment in the design. 3) Designing fail safe systems, particularly where they involve some energy source. 4) Developing systems to identify how variations in power supplies will affect the product, and allowing for them. 5) Designing products so they can be produced with a high degree of reliability, product after product, and developing manufacturing controls which will assure this sameness and reliability. 6) Using materials which are not readily combustible. 7) Eliminating sharp edges and corners and openings that can pinch. 8) Designing products that can withstand inexpert service or adverse transportation conditions. 9) Developing packaging which will both protect the product and keep children out of it. 10) Developing instructions, warnings, cautions which adequately communicate the presence of any potential hazards. 11) Developing techniques for product investigation and evaluation which provide the basis for adequate defense in product liability litigation. 12) And finally, participation in the development of rules and regulations relating to your product, and speaking up, if you don't like them, through your standards and trade associations.

Whether we may like it or not, the technical function must carry the prime responsibility for product safety. A systems effort, properly applied, can be a cost effective management tool with which to reduce potential hazards, accidents and damage; to reduce costly product recalls or field modifications, and to provide for early identification and control of potentially hazardous product in the field.

Rayford P. Kytle, Jr.

New Dimensions for Quality and Product Safety

Today's business climate demands that industry reassess its priorities. These are two important aspects that require top management attention, since failure to provide emphasis and support here could be disastrous.

"THE AMERICAN Consumer in a democratic society is a lot like the end result of crossing a tiger with a parrot—you may not like what the creature says, but when it talks, you had better listen."[1]

The consumer has spoken and continues to speak. The end result is new legislation which broadens and reinforces an irreversible trend—new ground rules and new burdens of regulations for businesses that deal in the marketplace. The new federal agency established in 1972, the Consumer Product Safety Commission, is an important and sometimes overlooked adjunct to an impressive array of governmental agencies affecting business in the marketplace. This agency has broad powers and has been referred to by many as having more far-reaching implications on businesses than does any other agency established to date. Its powers encompass imposition of an outright ban on the sale of a product, a product recall, repair or replacement by the manufacturer, and the creation of mandatory standards for product conformance. One of the Commission members has been quoted as saying, "When it involves a product that is unsafe, I don't care how much it costs the company to correct the problem."[2]

Product recalls, replacement, or repair are almost commonplace in today's headlines due to alleged defective or unsafe products in the market. When injuries occur, product liability suits may result; and the decisions being handed down by the courts are sizable and in some instances can literally bankrupt a company. A recent study by A.T. Kearney, Inc., states that product liability claims increased from $500,000 in 1965 to $12.5 billion in 1972 and are projected to increase to $50 billion in 1975.[3]

Alert businessmen are aware also that consumers now constitute what A.C. Nielsen terms "The New Silent Majority."[4] A study by Nielsen revealed that only 2% of the dissatisfied consumers write to the manufacturer; but by their refusal to buy that brand again, 34% impose a penalty far more severe than complaining.

The implications of the foregoing are such that successful businesses must reassess their priorities. For many years costs, service, and quality have been of prime import, but now an additional emphasis in the areas of quality and product safety is added. Perhaps the primary action for any company today is to evaluate the awareness of its management, and all pertinent groups, to the

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new demands for quality and product safety. Consideration should be given to a well-defined program to make certain that all echelons in the business are aware of the new concept of strict liability, recent decisions of the courts, the Consumer Product Safety Act, consumer attitudes, and the potential impact of all of this on their business. Existing products must be continuously evaluated in the changing climate of the market, of even more import are the factors to be evaluated when introducing a new product.

Many business firms are holding seminars conducted by their legal, insurance, and quality control and product safety personnel. Often these are conducted by in-house personnel and in other cases by the insurance carrier loss prevention people. Several of the large insurance companies have excellent presentations. Operating, sales, and technical managers are in attendance at these meetings. In addition, many companies are sending representatives to well-conducted product safety seminars conducted by the American Society for Quality Control, the Newark, New Jersey College of Engineering, the Defense Research Institute, and many other trade associations and groups.

> *"It is good to remember that in the event of legal action all records and files concerning the matter in litigation may be subpoenaed by the plaintiff's attorney."*

Excellent literature is available, and it is being disseminated to various levels of management. The Defense Research Institute; the Newark, New Jersey College of Engineering Product Liability Prevention Proceedings; the Research Institute of America; and the liability insurance carriers are among those who have publications that can be put to good use. Several visual presentations employing slides and commentary also are available. The Aluminum Association in New York City and the Liberty Mutual Insurance Company of Boston, Massachusetts have such available.

The need for development of management philosophy on quality and product safety is important. Even more important is that this philosophy result in a written policy statement indicating top management's objectives and beliefs concerning its products. This written document is becoming more prevalent in many firms today and clearly establishes a management directive on quality and product safety guidelines for all employees.

Many steps are involved in implementing a product quality and safety program. The program being developed in a large part of industry today starts by encompassing new horizons in design.

Design

Product design is not sufficient unless it embodies all aspects of safety pertaining to a given product. Management must take a new look at those involved in design, reviewing not only their effectiveness, but also their competency. The designer today is concerned with the efficient performance of a product, but he also must foresee the potential uses as well as abuses to which the product may be subjected. The design review today seeks to consider every conceivable way in which injury to persons or damage to property, as well as economic loss, might result from the product's use.

In instances in which a product's dangerous qualities may not be observed or commonly understood, prototypes are being built and subjected to in-house testing programs covering a variety of possible environments to which the product may be exposed. Feedback on product performance during the in-house test is being successfully employed to determine design improvement. Feedback is tabulated and recorded for review, decision, and corrective action.

Component analysis is vital during the in-house testing. Economic considerations also are evaluated. It is at this time that decisions regarding purchase of outside components should be made and specifications for such prepared. This should be followed by vendor analysis and selection. Specifications once set should be incorporated in the purchase order and the stipulation made that the supplier is to make no change in the product supplied unless the buyer is notified and the change is evaluated and approved. Determination of audits by the buyer and sampling plans and testing procedures for components as received must be set.

When the testing requirements have been satisfied, then the decision to subject the product to a limited market test is usually made.

Production Quality Control

Once the decision is made to produce the quantity for a market test, adequate production quality control measures are instituted. It is good to remember that the best design can be ruined if production is haphazard. To establish the parameters for adequate production quality control, the following are recommended and should be prepared in written form.

1. Minimum qualifications for inspection and quality control personnel should be set. These qualifications should be written and encompass not only the degree of technical knowledge and competence required, but also the physical requirements involved. Above all, such personnel should be given an eye examination and color blindness tests to make certain their vision meets satisfactory levels.

2. Detailed instructions for inspectors should be prepared. These instructions should be written in clear, concise language so that each inspector can clearly understand his duties and what is involved in performing his job satisfactorily. This is extremely helpful in training new inspection personnel.

3. Procedures for removal of obsolete drawings should be implemented. This involves setting up a system to make certain that all concerned have the latest revision of any drawing or specification. It also includes making certain that all drawings and specifications that have been superseded are removed. A central location to maintain a complete file on all changes for historical and record purposes should be designated. Failure to provide such a system could lead to errors.

4. Calibration of inspection equipment and intervals for calibration should be set. Recognized standards

against which calibration is to be made must be determined. The environment in which the instrument is used as well as the frequency of use must be analyzed. Logs for recording calibration intervals with dates the calibration was made and by whom should be provided and maintained for each instrument.

5. Frequency of tests should be set. Control charts and statistical sampling can be employed to help determine the frequency of each test to be made. It also is good to provide plans for monitoring the frequency and analyzing the data collected.

6. Detailed procedures for handling defective components and defective finished products should be set to make sure these do not get into the flow of good products. Well-defined areas designated for placement of defective products until disposition is resolved should be used. Successful employment of "Hold" tags and other designated attachments to defective products are often employed. Written procedures are helpful and should be explained and understood.

7. Determination of whether destructive testing or nondestructive testing should be made to assure quality and reliability. The type of tests employed should be determined by competent engineers. Much sophisticated nondestructive testing equipment is now available, and such should be employed where feasible.

8. Production worker training programs should be set. Well-organized training programs must be prepared so that each employee understands not only how to do his job, but also how his performance affects the total flow of good products. Defects are either man-made or machine-made, and no person should be assigned to a specific job until he is properly trained.

9. Maintenance schedules of production machines and tools should be determined so that they perform as desired. Statistical sampling of product output from each machine can be successfully employed to help set maintenance schedules. The environment in which the machine operates and the mechanisms subject to most wear must be analyzed. A good maintenance preventive program on fixed schedules aids greatly in the production of a good product.

In the limited market test, all aspects of management concerned with the product should be aware of the details. Procedures for feedback of information to pertinent groups must be determined. The insurance carrier should be advised. Procedures for handling customer complaints should be set. In addition, when the limited market test is performed, adequate technical personnel should be in the area to review immediately any instances of customer complaint or product failure. Photographs, samples of failed parts, and detailed write-ups should be forwarded immediately to concerned departments in the company. Constant review of the sale of the product, the problems in use of the product, and any reported failures of the product must be maintained in order to provide data for analysis and corrective measures.

> *"The job of labeling is becoming increasingly difficult, and the words which are used must be carefully chosen."*

Product Identification

As part of the production quality control system, codes for component parts and finished product are essential in the event of product recall. If there is no way of identifying dates of manufacture and shipment after the product is on the market and a small malfunction develops, large costs often can be incurred in isolating and correcting the defect. With only a few minutes of production time, proper identification can minimize the number of items recalled if the cause of the malfunction can be determined to have been produced between an interval of time on a given date, on a given machine, and so on. Product recall procedures should be prepared and thoroughly understood by all concerned.

It is good to remember that in the event of legal action all records and files concerning the matter in litigation may be subpoenaed by the plaintiff's attorney. This emphasizes the need to evaluate record retention procedures, and decisions should be made as to what records will be retained and where they will be retained, as well as how long they will be retained.

Areas evaluated in this regard should involve:

1. All design records, particularly those involving design changes made to improve the performance of the product.

2. If one design has been accepted over others, full documentation as to why the design was accepted is advisable.

3. Results of tests conducted on the product as well as on its components should be maintained.

4. Production lot tickets which keep track of the manufacturing process of the item and reveal such facts as date of manufacture, personnel performing tests, and so on, should be considered for retention.

5. Field performance records—information concerning the product after it is in use—also are desirable to maintain. This information should include a summary of each service call, giving the reason, a detailed listing of any repairs, a statement as to whether the product was being used correctly, and any notations regarding safety devices having been removed or altered.

6. An index showing where all records are maintained and which records are maintained is desirable.

Determination of how long to retain adequate records poses a real problem, and consideration of all factors involved is necessary. It must be remembered that the statute of limitations often may not commence when the product is shipped, but when a defect causes injury to persons or damage to property.

Instructions, Labeling, Packing

Perhaps one of the most important areas is concerned with product use instructions, labeling, and warnings.

Whether a product is for industrial or consumer use, proper labeling is important. However, the job of labeling is becoming increasingly difficult, and the words which are used must be carefully chosen. All labeling should be reviewed by legal counsel, expecially for those products about which there may be a legal duty to inform the user. Naturally, legal counsel should be asked to check compliance with federal, state, and local laws and regulations. It even may be necessary to incorporate warnings as to how the product is not to be used. Many industry associations have valuable information available concerning labels, and it may be good to keep advised of the industry association's assistance in this regard.

All instructions, whether they are on the carton, packing case, or in the form of instruction manuals, must be evaluated. Important questions to be covered are:

1. Do the instructions advise of dangers inherent in the use of the product?

2. Does the instruction manual adequately describe safe methods of assembling if same is performed by purchaser?

3. Are the instructions clear, concise, and easily understood by the persons most likely to need them?

4. If maintenance or service instructions are included, is the user alerted to potential dangers in using unauthorized parts when repairs are necessary?

One area of utmost importance here is to make certain that sales personnel are properly instructed and do not make exaggerated or unauthorized claims, either oral or written, regarding product performance which could lead to unexpected liability.

Perhaps of equal importance is evaluation of the packing and packaging procedures. Packing standardization assists greatly in making certain that all applicable components, as well as instruction manuals, and so on, are included in each package.

Advertising

All advertising, sales and promotional material, and publicity releases should be evaluated by technical and legal personnel, and procedures must be established for review by them. Legal review of advertisements and sales literature for undesirable product claims or inferences can minimize potential legal booby traps. Technical personnel also can be used to deter overenthusiastic marketing or advertising personnel from making statements or claims that cannot be technically substantiated. One of the most important accomplishments from this kind of review and evaluation is to prevent the use in sales literature of photographs which portray potentially hazardous uses of the product.

Warranties, Guarantics, Disclaimers

On January 4, 1975, the 93rd Congress enacted a new federal law governing warranty practices. The new law, Title I of The Magnuson-Moss Warranty-Federal Trade Commission Improvement Act, sets forth minimum federal standards for written warranties. It also requires that each warranty be designated "full" or "limited," limits disclaimers of implied warranties, and sets procedures for the Federal Trade Commission pertaining to warranties. It further suggests procedures for settling warranty disputes.

This Act has created great activity among manufacturers and retailers to revise their warranty policies and practices, and knowledge of the basic provisions of this Act by management is vitally important. It is critical that legal counsel approve all warranties and disclaimers before they are issued, as well as when they are revised for any product. It is important that counsel have the best advice of the appropriate technical personnel. In addition, marketing and advertising should ensure that any claims made in advertising do not exceed those contained in the written product warranty.

The responsibility every business has to its customers and the public today is great. Uppermost in mind at all times must be the thought to make quality products that can be safely marketed and used. New dimensions for quality and product safety are demanded if business is to minimize large economic losses.

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1. Alexander M. Schmidt, Commissioner of the Food and Drug Administration, before the National Canners Association board meeting, Spring 1975.

2. Murray L. Weidenbaum, *Government-Mandated Price Increases* (Washington, D.C., American Enterprise Institute for Public Policy Research, 1975), p. 32.

3. A.T. Kearney, Inc., *Managing in a 'Consumer' Economy, a Research Study on Product Quality and Safety* (Chicago, A.T. Kearney, Inc., 1975), p. 4.

4. A.C. Nielsen Co., *A Study of Consumer Attitudes Toward Quality* (Chicago, A.C. Nielsen Co., 1975), p. 8.

FEDERAL BAR JOURNAL

CONSUMER PRODUCT SAFETY: THE CURRENT RECORD OF ADMINISTRATIVE INTERPRETATION

By Judy Feinberg

Congress created the Consumer Product Safety Commission (hereafter, CPSC, or the commission) on October 27, 1972, as an independent regulatory agency, headed by five commissioners, to protect consumers against unreasonable risks of injury or death caused by substantially hazardous products used in or about the home.[1]

CPSC was established as a direct result of the recommendations and findings of the National Commission on Product Safety.[2] This commission reported that 20 million Americans are injured each year in incidents involving consumer products. Of the victims, 30,000 are killed, 110,000 are permanently disabled. Based upon this evidence, Congress empowered CPSC with the legal machinery to regulate manufacturers, distributors, retailers, private labellers, importers, and others affected. This article discusses the current state of administrative implementation of consumer product safety legislation during the past five years.

The commission exercises its safety function under five statutes.[3] To assure that the products covered by the law are safe, CPSC has the authority to set safety standards, ban hazardous products, require bookkeeping, examine records, call for reports, inspect business premises, impose labelling and warning requirements, and demand safety certification.

Enforcement is effected by court injunctions,[4] seizure of hazardous

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[1] Pub. L. No. 92-573; 86 Stat. 1207 (1972).

[2] National Commission on Product Safety, *Final Report* (1970).

[3] (1) The Consumer Product Safety Act (CPSA), the enabling statute, which authorizes the promulgation of a consumer product safety rule and identification of a substantial product hazard. 15 U.S.C. §§ 2051-2081 (Supp. V 1975).

(2) The Flammable Fabrics Act of 1953 (FFA) which authorizes the establishment of flammability standards for articles of wearing apparel, children's sleepwear, mattresses, carpets and rugs. 15 U.S.C. §§ 1191-1204 (1970). These standards are enforced by the CPSC under § 5 of the Federal Trade Commission (FTC) Act, which prohibits unfair and deceptive trade practices. 15 U.S.C. § 45 (1970 and Supp. V 1975)

(3) The Federal Hazardous Substances Act (FHSA) which directs the administering agency to declare and ban hazardous substances such as dangerous toys and fireworks from interstate commerce and to require labelling of hazardous products in or about the household. 15 U.S.C. §§ 1261-1274 (1970).

(4) The Poison Prevention Packaging Act (PPPA), under which the commission has developed special packaging standards for hazardous household substances to protect children from injury or illness by handling, using or ingesting them. 15 U.S.C. §§ 1471-1476 (1970).

(5) The Refrigerator Safety Act (RSA), which requires household refrigerators shipped in interstate commerce to be equipped with a device, conforming to specific standards, that enables the door to be opened easily from the inside. 15 U.S.C. §§ 1211-1214 (1970). See CPSC Directives for Enforcement of the Refrigerator Safety Act, CPSC Order No. 9020.1 (June 7, 1974).

[4] CPSA § 22, 15 U.S.C. § 2071 (Supp. V 1975); FFA § 6(a), 15 U.S.C. §1195(a) (1970); FHSA § 8(a), 15 U.S.C. § 1267 (1970). Products regulated under PPPA become a hazardous substance and are subject to the remedies of FHSA. PPPA § 2(2)(A), 15 U.S.C. § 1471(2)(A) (1970).

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products,[5] criminal sanctions, and administratively by imposition of civil penalties.[6]

Remedial devices imposed to correct product violations vary under the different acts. The Federal Hazardous Substances Act (FHSA), Poison Prevention Packaging Act (PPPA), and Consumer Product Safety Act (CPSA), provide for a "refund" remedy. Under FHSA and PPPA, the manufacturer, distributor, or dealer must repurchase any product sold which has been banned as a hazardous substance and reimburse the consumer for any necessary transportation expense.[7] Under CPSA, a manufacturer, distributor, or retailer who has sold a hazardous product may elect either to offer a refund of the purchase price, less a reasonable allowance for use if the consumer has had the product for at least one year; to repair; or replace the product so it will conform to safety requirements.[8] The notice and repurchase provisions of Section 15 of CPSA are more flexible than those of FHSA and may be enforced through civil penalties.

Under the Flammable Fabrics Act (FFA) the commission has the authority to issue a cease and desist order[9] for articles of wearing apparel and fabrics moving in commerce which are so highly flammable as to constitute an unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. In contrast to FHSA, PPPA, and CPSA, the Flammable Fabrics Act does not explicitly provide for a refund to consumers. Whether or not the commission, as successor to the Federal Trade Commission (FTC), has the power to recall flammable fabrics from the consumer is presently under consideration.[10] The power to recall flammable carpet from distributors and retailers has been asserted and is presently on appeal in the Ninth Circuit.[11]

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[5] CPSA § 22(b), 15 U.S.C. § 2071(b) (Supp. V 1975); FFA § 6(b), 15 U.S.C. § 1195(b) (1970); FHSA § 6, 15 U.S.C. § 1265 (1970). These sections basically regulate the commission's seizure power, governed by the rules of in rem admiralty. CPSC investigators do not have the authority to seize the goods themselves. They may, however, institute a proceeding by process of libel for the seizure and confiscation of hazardous products in any district court of the United States where the goods are located. The clerk of the U.S. District Court without a judicial hearing issues an order of arrest authorizing a United States marshall to seize the goods. The United States marshall must publish notice of seizure on goods and in local newspapers. The claimant then may seek a judicial determination on the issue of seizure. If no claim is asserted the goods are destroyed.

[6] CPSA § 20, 15 U.S.C. § 2069 (Supp. V 1975), FFA § 7, 15 U.S.C. § 1196 (1970); FHSA § 5, 15 U.S.C. § 1264 (1970). Although § 20 of CPSA does not expressly confer jurisdiction on civil penalties upon either the federal district courts or the commission, the latter has recently instituted a civil penalty procedure whereby the agency will in an expedited proceeding assess the amount for violations according to formal APA requirements. See *Atlas Roofing Co. v. OSHRC*, U.S.L.W. (No. 75-746), where the Supreme Court also in deciding *Irey v. OSHRC*, (No. 75-748) unanimously affirmed the lower courts' rulings that upheld the administrative assessment of penalties before an administrative law judge without a jury trial. See 29 U.S.C. § 654(c).

[7] FHSA § 15, 15 U.S.C. § 1274 (1970).

[8] CPSA § 15(d)(1)(2)(3), 15 U.S.C. § 2064(d)(1)(2)(3) (Supp. V 1975).

[9] FFA § 5(b), 15 U.S.C. § 1194(b) (1970), incorporates the enforcement powers of the FTC Act, 15 U.S.C. § 45 (Supp. V 1975).

[10] Two cases were orally argued before the commission on March 14, 1977, on appeal from an administrative law judge's ruling that, absent a CPSA § 30(d) finding (discussed *infra* at note 33), the commission does not possess authority under FFA or the FTC Act to order a recall, repair, or refund of carpet actually installed on the consumers' floor. See *Barrett Carpet Mills, Inc.*, CPSC Docket No. 75-5, Initial Decision of Administrative Law Judge Paul N. Pfeiffer, (July 8, 1976); Northwick Carpet Mills, Inc., CPSC Docket No. 76-6, Initial Decision of Administrative Law Judge Paul N. Pfeiffer (Sept. 7, 1976) (order granting partial summary judgment Nov. 9, 1976). Westland Carpet Mills, Inc. CPSC Docket No. 75-21, Initial Decision of Administrative Law Judge Paul N. Pfeiffer (Sept. 7, 1976) was withdrawn from oral argument before the commission but was submitted for decision based upon the record and briefs.

[11] *In re Congoleum Industries Inc.*, FTC Docket No. 8896. (1974); appeal pending No. 75-3112 (9th Cir. Feb. 18, 1976).

The rules, regulations, standards, and test methods authorized under these five acts are enforced by a voluntary corrective action plan (CAP), a consent order, or administrative litigation.[12] After a formal hearing before an administrative law judge, a litigant can appeal to the commission whose decision is subject to judicial review in the appropriate federal circuit court of appeals.

I. The Consumer Product Safety Act

The purposes of CPSA are to protect the public against unreasonable hazards associated with consumer products,[13] to assist consumers in evaluating product safety, to develop uniform consumer product standards, and to promote product safety research.[14] Congress recognized the need for a comprehensive federal consumer product safety program to balance the equities between the consumer and the manufacturer,[15] finding that the competitive marketplace forces were not strong enough to promote industry self regulation as the consumer's appetite for technologically advanced products increased. Thus, the commission was established as a safety agency with the objective of identifying and removing unsafe products from commerce.

The commission regulates substantial product hazards under section 15 of CPSA, the tattletail provision.[16] This section requires manufacturers, distributors and retailers to notify the commission when a product fails to comply with an applicable consumer product safety rule[17] or contains a defect which could create a substantial product hazard.[18]

Government and industry are at odds over the obligation under this provision. Manufacturers are loosely construing their duty to report. Many times manufacturers are not negligent in notifying the commission, but rather fail to do so only because they do not think their product creates a substantial hazard. Manufacturers believe the initial judgment rests with them. In contrast, under the new proposed regulations, government imposes a duty on manufacturers to report whenever the possibility exists that a product *could* create a substantial hazard.

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[12] No litigated cases have appeared under RSA nor PPPA, but the latter has been interpreted in consent agreements.

[13] A consumer product has been broadly defined as any article or component produced or distributed for use in or around a household, a school, or in recreation. CPSA § 3(a)(1). 15 U.S.C. § 2052(a)(1) (Supp. V, 1975). However, one federal district court recently held that although aluminum wire may be purchased by consumers and installed in homes, such is not ordinarily a consumer product "for use in or about a permanent or temporary household or residence" within the meaning of § 3(a)(1) of CPSA and, therefore, the commission lacks jurisdiction.

Kaiser Aluminum & Chemical Corporation v. U.S. Consumer Product Safety Commission No. 76-44 (D. Dela. March 11, 1977). *But see United States v. The Anaconda Co.*, No. 77-0024 (D.D.C., June 15, 1977), *appeal pending* No. 77-1628 (D.C. Cir.) (discussed *infra*).

[14] CPSA § 2(b)(1) –(4). 15 U.S.C. § 2051(b)(1)—(4) (Supp. V 1975).

[15] H. Rep. No. 1153, 92d Cong., 2d Sess. 27, § 2(a)(1972)

[16] CPSA § 15. 15 U.S.C. § 2064 (Supp. V 1975).

[17] A consumer product safety rule respecting the risk of injury associated with a hazardous product is promulgated within 60 days after publication in the *Federal Register* for public comment. Once a rule or standard becomes effective, every manufacturer or private labeller of a product which is subject thereto shall issue a certificate to their distributors or retailers to the effect that such product conforms to all applicable consumer product safety standards, and shall specify any standard which is applicable. If the product fails to comply to an applicable safety rule or contains a defect which could create a substantial hazard, the manufacturer, distributor or retailer must immediately notify the Commission of such conditions, unless they have actual knowledge that the Commission has been adequately informed of such defect or failure to comply. CPSA § 9(a)(1)(A)(B), § 14(a)(1), § 15(b)(1)(2), 15 U.S.C. § 2058(a)(1)(A)(B), § 2063(a)(1), § 2064(b)(1)(2) (Supp. V 1975).

[18] The CPSC Division of Product Defect Identification was formed on March 15, 1974, to regulate notices of defects, record the progress of remedial efforts by the manufacturers, recommend closing of files on individual notices of defects when remedial efforts are judged or have been completed, screen consumer complaints and other sources for possible defects and notify manufacturers and identifiable components of the consumer product distribution system of potentially substantial product hazards of their products.

In most instances, once a manufacturer, distributor, or retailer either notifies the commission or receives notification from it that his product may involve defects posing substantial product hazards, he agrees to a voluntary corrective action plan to recall the noncomplying product and to offer repair, replacement, or refund to the consumer less a reasonable allowance for use.

If a manufacturer refuses to undertake voluntary corrective action, a prehearing conference is scheduled to dispose of the matter. A consent agreement has a similar effect as a voluntary corrective action plan except that a commission order is imposed.[19] Since consent agreements are signed and accepted by the commission, a cease and desist order is usually issued concurrently. A civil penalty can be imposed for a violation of that order.

If neither a voluntary corrective action plan nor a consent agreement has been reached, then the parties go to hearing under section 15(c) of CPSA.[20] The matter of criminal penalties has been reserved by the statute for court action. Civil penalties may be imposed after an expedited administrative hearing procedure.[21]

The commission's most effective enforcement efforts have been in section 15 cases.[22] During 1976, the commission processed by consent order 140 possible substantial product hazard cases: 59 were initiated by the staff and 81 were voluntarily reported by manufacturers, distributors, and retailers. This method of enforcement reaches the objective of removing an unsafe product without expense of litigation. The litigated cases under CPSA are few in comparison to the number of voluntary corrective action plans and consent orders. Manufacturers fearing the impact of government regulation by public hearing, often with slight chance of success, have been willing to comply in lieu of litigating. In all of the cases, whether litigated or (with the exception of the case of *White Consolidated Industries, Inc.*[23]), the result has been the same: the manufacturer, distributor, or retailer has either repaired or replaced the offending product or refunded the purchase price.

The commission initiated a proceeding in 1975 against White Consolidated Industries, Inc., alleging that approximately 336,000 Kelvinator refrigerators manufactured between 1970 and 1974 presented a substantial product hazard within section 15(a)(2) of CPSA, due to an alleged design defect in the refrigerator defrosting system which could cause fire and resultant injury.

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[19] The commission has approved the remedies of repairing unsafe products with new and improved safety attachments, additional testing, replacing hazardous products with safe products, or refunding the purchase price upon return of the defective product. See *In re McCulloch Corporation*, CPSC Docket No. 74-1, May 6, 1974. *In re National Industries, Inc.*, CPSC Docket No. 74-2, May 19, 1974. *In re Spray Tech Corporation*, CPSC Docket No. 75-7, October 14, 1975. The *Aluminum Baseball Bats* cases, CPSC Docket No. 75-9, 10, 11, 12, 13, 14, February 13, 1976. *In re Terranan Industries, Inc.*, CPSC Docket No. 76-C0028, June 28, 1976. The *Kite* cases, CPSC Docket No. 75-15, 17, 18, 19, April 1, 1976.

[20] 15 U.S.C. § 2064(c) (Supp. V 1975).

[21] See discussion in note 6, *supra*.

[22] Approximately 500 plans have resulted in more than 6.3 million products being corrected. The commission is placing greater emphasis on seeking out unreported product defects which could present substantial product hazards and on evaluating the timeliness of defect reports which were received.

[23] CPSC Docket No. 75-1 (Nov. 3, 1975)

The presiding officer found that the design was defective, but did not find a high probability of substantial hazard existing in any given Kelvinator refrigerator since none of the field incidents involved a serious fire resulting in injury. No appeal was filed by the staff from the initial decision, and the case was dismissed by the full commission.

The second litigated case reviewed by the commission was *In re Relco, Inc.*,[24] affirming the administrative law judge's interim initial decision[25] which held that WelDex electric arc welders presented a substantial product hazard in terms of potential electric shock, burns, and fire due to certain design and performance defects. The administrative law judge's initial decision ordered respondents to stop the manufacture and distribution of the product, to give public notice of the dangers presented, and to offer replacement welders or refunds. Further proceedings were held on the question of the proper amount of refund where the consumer possessed the welder for more or less than one year.[26]

On appeal, the Commission modified the order on two counts:

> (1) The commission provided that tender of the welder or its vital parts should be mandatory for all persons seeking a refund regardless of how long it has been possessed.[27]
>
> (2) The commission required that an affidavit of disposal for safety reasons be tendered the manufacturer by all claimants prior to refund.

In addition, the commission required proof of purchase to be submitted with the affidavit and required that detailed and illustrated instructions for dismantling the welder be included in the recall letter sent to consumers.

The commission's third litigated section 15 case under CPSA was *In re Francis Alonso, Jr.*, d/b/a Mylar Star Kites. The administrative law judge found that the aluminized polyester film kites with long, aluminum-coated tails though not *per se* dangerous, presented an electric shock hazard to the user and the public when entangled in high voltage overhead electrical power transmission lines.[28] The administrative law judge concluded that labelling and warning literature was insufficient to eliminate the risk and ordered respondents (1) to give public notice of the hazard; (2) to cease and desist from further manufacture of kites made of conductive material; and (3) to elect to replace any metallized polyester film kites with tails returned to them by their customers with a nonmetallized kite or refund the purchase price.[29] Repair was conceded to be impracticable. On appeal, the commission concurred with the administrative law judge's findings as to the hazardous nature of the aluminized kites. However, the commission dismissed the case for lack of jurisdiction. The majority held that since aluminized kites are articles intended for use by children, the action should have been brought under FHSA.[30] Moreover, respondent will be free to manufacture and sell aluminized kites until a rule regarding all aluminized kites under FHSA can be undertaken. Commissioner Kusher pointed out in his dissent "that the respondent has been allowed to avoid an order which has been applied to other respondents, who are no more or less guilty of having manufactured a product judged to be a substantial hazard."[31]

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[24] CPSC Docket No. 74-4 (Final Order issued Oct. 27, 1976).

[25] CPSC Docket No. 74-4 (April 29, 1975).

[26] The administrative law judge found that the usable life of the welder was approximately one year and ordered: (a) A consumer who possessed the welder for less than one year from the date of notice was entitled to a full refund regardless of whether or not he tendered the product or the internal components. (b) A consumer who possessed the welder for more than one year at the time of notice of the hazard and tendered it together with unused or partially used rods was entitled a full refund of his purchase price including shipping costs. (c) A consumer who possessed the welder for more than one year at the time of notice of the hazard and who tendered the welder without rods was presumed to have obtained considerable benefit from the device and is, therefore, entitled to a refund of 50% of his total purchase price, plus shipping costs. (d) A consumer who disposed of the welder after recognizing its unsafe character and executed an affidavit to that effect was entitled to a refund of 50% of his total purchase price plus shipping costs. (e) A consumer who ignored the commission's or manufacturer's notice that the welder was hazardous and continued to use it, or makes it available to others, or disposed of it for other than safety reasons was not entitled to any refund. CPSC Docket No. 74-4, Amended Initial Decision and Order on Reopened Proceeding (April 5, 1976).

[27] CPSC Docket No. 74-4, Final Order (October 27, 1976), pp. 4-8. The commission relying on strong congressional intent and the statutory purpose of § 15 to protect the public by encouraging removal of dangerous products from the consumer's homes, ordered tender whenever practicable and where no danger is presented in the tender process. See H. Rep. No. 92-1153, 92d Cong., 2d Sess. 43 (1972). The commission agreed with the difference in refund allowed by the administrative law judge based on the time of possession and the use received for persons in possession over one year. See discussion in note 26, *supra*. The commission also agreed that § 15 mandates a full refund to persons in the under-one-year's possession category. See CPSA § 15(d)(3), 15 U.S.C. § 2064(d)(3) (Supp. V 1975).

The "toy debate" is a perfect illustration of the problem associated with the interrelationship of CPSA and FHSA. At the time of this proceeding, Section 30(d) of CPSA required the commission to proceed under FHSA rather than CPSA if the risk of injury could be remedied under FHSA.[32] Today, the commission has greater flexibility under the amended Section 30(d)[33] to regulate the risks of injury associated with consumer products under the various acts through CPSC procedures and remedies, if it finds by rule that such is in the public interest. Thus, the commission had the option to proceed under the more flexible repurchase provision of section 15 of CPSA. Thus the jurisdictional gap between CPSA and FHSA can be greatly reduced.

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[28] Alonso was one of five respondents charged with manufacturing or distributing hazardous metallized kites, but four cases were settled by consent agreement; only Alonso requested a formal administrative hearing. CPSC Docket No. 75-16, Initial Decision and Order (June 21, 1976), p. 11.

[29] Tender of a usable kite was made a condition precedent to refund unless an affidavit of disposal solely for safety reasons was submitted. A damaged kite was not considered to represent a continuing hazard. *Id.* at 16-17.

[30] CPSC Docket No. 75-16, Appeal from Initial Decision, (July 20, 1976).

[31] CPSC Docket No. 75-16, Dissenting Opinion of Commissioner Lawrence M. Kushner (Sept. 26, 1977), p. 4.

[32] Congress intended that the commission consider all aspects of the risk of injury, together with the remedial powers available to it under both the bill and the other Acts. 15 U.S.C. § 2079(d) (Supp. V 1975).

[33] The amendment provides:

> A risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act [15 USCS §§ 1261 et seq.], the Poison Prevention Packaging Act of 1970 [15 USCS §§ 1471 et seq.], or the Flammable Fabrics Act [15 USCS §§ 1191 et seq.] may be regulated under this Act only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under this Act. Such a rule shall identify the risk of injury proposed to be regulated under this Act and shall be promulgated in accordance with section 553 of title 5, United States Code [5 USCS § 553]; except that the period to be provided by the Commission pursuant to subsection (c) of such section [5 USCS § 553(c)] for the submission of data, views, and arguments respecting the rule shall not exceed thirty days from the date of publication pursuant to subsection (b) of such section [15 USCS § 553 (b)] of a notice respecting the rule. 15 U.S.C. § 2079(d), as amended by Act of May 11, 1976, Pub. L. No 94-284, §§ 3(f), 16, 90 Stat. 504, 510.

II. THE FEDERAL HAZARDOUS SUBSTANCES ACT

The purpose of FHSA is to protect the public health and safety by either requiring labelling of hazardous products for use by children or adults in or about the household[34] or, notwithstanding the cautionary labelling,[35] to ban the hazardous substances by keeping them out of commerce due to the degree or nature of the hazards involved.[36] Certain products, however, are exempt under this act since they are covered by other regulatory legislation.[37]

Under FHSA, once an article or substance is deemed a banned or misbranded hazardous substance, the commission notifies the manufacturer, distributor, or dealer of the statutory or standard violation. The commission also advises these parties to apply the correct labelling, to recall the hazardous product, or bring the product into compliance. Section 15 of FHSA requires the manufacturer, distributor, or retailer to repurchase the banned hazardous substance from the consumer and to refund the purchase price paid for the article or substance plus reasonable and necessary transportation expenses.[38] Under the repurchase provision, signs are required to be posted in stores carrying the banned hazardous substance in order to notify consumers that they are entitled to a refund. Since the commission has no authority to issue an administrative order to recall, if the manufacturer, distributor, or dealer does not voluntarily repurchase the item, then the commission can obtain a court order to seize the products or subject the manufacturer, distributor, or dealer to a penalty for introducing into commerce a banned or misbranded hazardous product.[39]

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[34] 15 U.S.C. §§ 1261(p)(1)(2) (1970) states that a hazardous substance will be "misbranded hazardous substance" unless a label bears the following information:

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic, (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards such as "Flammable," "Combustible," "Vapor Harmful," "Causes Burns," "Absorbed Through Skin," or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to Section 3; (G) instruction, when necessary or appropriate for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h); (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from and the hazard, and

(2) On which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

[35] The Commission may also establish by regulation reasonable variations of additional labelling requirements, if the minimum cautionary labelling is not adequate for the protection of the public health and safety in view of the special hazard presented by any particular substance. 15 U.S.C. § 1262(b)(1970).

[36] 15 U.S.C. § s1261(g)(1) (1970).

[37] Under 15 U.S.C. § 1261(f)(2)-(3) (1970), certain items exempt from the definition of a "hazardous substance" include: economic poisons within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act; foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house; any source material, special nuclear material or byproduct as defined in the Atomic Energy Act of 1954 as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

[38] 15 U.S.C. § 1274 (1970).

[39] 15 U.S.C. § 1264, 1265 (1970).

This alternative places a heavy economic burden upon the noncomplying manufacturer, distributor, or dealer. The justification, however, lies in the fact that the parties in the chain of distribution placed an unsafe product into commerce and realized a profit.

Banned Products

From May 14, 1973 through March 10, 1977, 202 manufacturers have recalled the following banned hazardous products:[40]

Product	*Number of Manufacturers*
Toys[41]	138
Record player[42]	2
Rock polisher	1
Train set	1
Cribs[43]	2
Vinyl chloride[44]	11
Lead paint[45]	44
Silver solder with cyanide[46]	1
Carbon tetrachloride[47]	1
Benzene in plastic balloons[48]	1

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[40] J. Samalik, Bureau of Compliance Report (1976), Bethesda, Maryland.

[41] Under § 2(f)(1)(D) of the act any toy or other article intended for use by children which the commission by regulation determines, in accordance with § 3(e) of the act presents an electrical, mechanical, or thermal hazard is deemed to be a banned hazardous substance and is subject to § 15 repurchase. Under the regulations the commission has determined which types of toys or other articles intended for use by children present a mechanical hazard within the meaning of § 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacturer presents an unreasonable risk of personal injury or illness. These types of banned toys and other banned articles intended for use by children have been subject to recall. FHSA § 2(f)(1)(D), 15 U.S.C. § 1261 (f)(1)(D) (1970). See also 16 C.F.R. § 1500.18(a) (1976).

[42] The record players, rock polisher and train set were recalled for failure to meet the requirements for electrically operated toys or other electrically operated articles intended for use by children. 16 C.F.R. § 1500.18(b) (1976).

[43] A full size baby crib which is defined in 16 C.F.R. § 1508.1 (1976) as a bed (1) that is designed to provide sleeping accomodations for an infant, (2) that is intended for use in the home, and (3) that is within a range of ±5.1 centimeters (± 2 inches) of the interior length or width dimensions specified for full size baby cribs in § 1508.3 and does not meet the requirements of § 1508 is deemed to be a toy presenting a mechanical hazard. 16 C.F.R. § 1500.18 (a)(13) (1976).

[44] The commission classified all self-pressurized household products containing vinyl chloride monomer as a banned hazardous substance. Most manufacturers have agreed to recall such products. However, Pactra Industries, Inc., appealed the commission's ruling to the Ninth Circuit which set aside the rule holding that a formal hearing is required as part of the rule-making procedure where a controversial issue is involved, *Pactra Industries, Inc. v. Consumer Product Safety Commission*, Nos. 74-2902, 74-3168 (9th Cir. May 2, 1977).

[45] The commission has deemed that items intended for use by children or packaged in a form suitable for use in or around the household and containing paint with more than 0.5% lead content are subject to banning procedures of repurchase. 16 C.F.R. § 1500.17(a)(b)(i)(B) (1976).

[46] Silver solder containing a concentration of cyanide greater than 25 parts per million are deemed to be a banned hazardous substance and are subject to repurchase. This excludes unavoidable manufacturing residues of cyanide sales in other chemicals that under reasonable and foreseeable conditions of use will not result in a concentration of cyanide greater than 25 parts per million. 16 C.F.R. § 1500.17 § (a)(5) (1976).

[47] Atmospheric concentration of carbon tetrachloride and mixtures containing it (including carbon tetrachloride and mixtures containing it used in fire extinguishers) greater than 10 parts per million are banned hazardous substances and are subject to repurchase. This excludes unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million. 16 C.F.R. § 1500.17(a)(2) (1976.

[48] CPSC recalled plastic ballon toys deemed to be a hazardous substance. Due to an error by the manufacturer, the product contained benezene which, over an extended period of time, could cause a type of blood disorder known as dyscrasias. The distributor voluntarily agreed to offer a full refund to purchasers upon tender of the hazardous item. 16 C.F.R. § 1500.14(a)(3) (1976).

Labelling

Hazardous substances intended for use in the household or by children are subject to the labelling requirements of Section 2(p) of the act. If the labelling requirement has not been met, then the hazardous substance is termed a "misbranded hazardous substance."[49]

From May 14, 1973 through March 10, 1977, 41 manufacturers have recalled misbranded hazardous substances for improper labelling.[50] A misbranded hazardous substance is not subject to section 15 repurchase. Most manufacturers will either recall the misbranded hazardous substance or utilize the required label. The following includes a breakdown of the misbranded hazardous substances which have been recalled due to improper labelling:

Product	*Number of Manufacturers*
Spray adhesives	5
Drinking birds	4
Cyanocrilite glues	5
Jequirity beans	4
Petroleum distillates—including thinners, removers, cleaners, etc.	17
Dry masonry paint	1
Dry masonry cleaner (HC1)	1
Self-pressurized container	1
Adhesives/glues	2
Microscope set	1

Rule-Making Proceedings

In contrast to the other acts, the commission is required to hold a formal hearing prior to promulgating a regulation banning a substance as hazardous if reasonable grounds exist.[51] To date, the commission has published final banning and safety regulations for fireworks devices, baby pacifiers, and a ban on children's garments and fabrics containing the flame-retardant chemical Tris.

The first formal rule-making proceeding[52] involved proposed regulations governing labelling, performance standards, and banning of certain Class C fireworks.[53] The proceeding ultimately evolved into two major issues: the first included proposals to strengthen the regulation by banning all firecrackers and/or tightening the labelling and performance requirements;[54] and the second included proposals to weaken the regulation by elimination of the ban on firecrackers, clarification of the requirements relating to color and/or configuration of toy smoke and flitter devices, and a proposed grace period to dispose of noncomplying fireworks inventory.[55]

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[49] 15 U.S.C. § 1261(p)(2) (1970).

[50] See note 40, *supra*.

[51] Proceedings for the issuance, amendment, or repeal of regulations are governed by sections 701(e), (f), (g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371 (e), (f), (g) (June 25, 1938). See FHSA § 3(a)(2), 15 U.S.C. § 1262(a)(2) (1970).

[52] CPSC Docket No. 74-3 (1974).

[53] 39 Fed. Reg. 17435-17440 (1974).

In his initial decision the administrative law judge concluded that the degree and nature of the hazard involved in using fireworks, primarily malfunction, did not warrant a total ban to protect the public health and safety. Instead the administrative law judge recommended a restriction limiting the powder content of Class C firecrackers to 1.2 grains of flashpowder or up to 2 grains of nitrate and aluminum flashpowder or nitrate and carbon powder. Improved visual and timed fusing, labelling, and packaging requirements to prevent fuse damage in transit were made applicable to all Class C firecrackers. The administrative law judge also concluded that no age limitation for use by children should be implemented but suggested that adults insure proper supervision of children in the use of fireworks.[56]

On June 7, 1976, the commission in a tentative 3-2[57] decision issued its final regulation. It lowered the permissible explosive charge in firecrackers instead of banning them[58] as originally proposed and established performance standards and labelling requirements for other fireworks devices sold or distributed for consumer use.[59] The commission found that firecrackers and other fireworks devices are "hazardous substances" within the meaning of 2(f)(1) of FHSA.[60] The commission determined that firecrackers containing more than 50 milligrams of pyrotechnic composition could not be remedied through cautionary labelling and thus are banned hazardous substances. Firecrackers under 50 milligrams were permitted upon a finding that the public health and safety would be protected by adequate labelling.[61] The regulation became final by a 2-2 vote, the chairman, who had not won reappointment, having resigned.

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[54] The proponents of banning fireworks argued that because of their explosive characteristics, firecrackers are inherently dangerous, they cause the largest percent of fireworks injuries particularly among children in daylight hours when adults are not present. Notwithstanding cautionary labelling or performance standards, protection of public health and safety can only be assured by prohibiting the distribution of all Class C firecrackers in interstate commerce. The Fire Marshals Association of North America proposed a total ban on the sale, possession or use of firecrackers with the exception of toy paper caps in order to have workable enforcement. The availability of fireworks sold in the United States can be illustrated by the importation of between 1.1 billion and 4 billion firecrackers annually and the sale of 500 million sparklers with minimum advertising.

[55] The opponents of the ban favored weakening the regulation and argued that a fuse designed to prevent premature and delayed ignition and which permits the user to follow the flame visually as it progresses toward the cylinder so as to facilitate "get away" before detonation, is reasonably safe. In addition, they argued that the explosive power of the firecracker can be reduced by changing from flash to black powder and cutting back on the amount contained in the cylinder. Nitrate flash powder which is visually attractive but less powerful than pure flash powder was proposed as an intermediate ground. The opponents of the ban desired local regulation over a total federal ban which they believed to be unenforceable and pointed out that the number of injuries from Class C firecrackers was not substantial and that in reporting fireworks injuries, unlawful Class B and legal Class C firecrackers were frequently commingled.

[56] The administrative law judge recommended that the proposed regulation be strengthened by substituting for the proposed label "USE ONLY UNDER CLOSE ADULT SUPERVISION" the following (APPROPRIATE SYMBOL DEPICTING INJURY OR DEATH)—"DANGER—MISUSE MAY CAUSE INJURY—NOT RECOMMENDED FOR USE BY CHILDREN UNDER 14 YEARS UNLESS CLOSELY SUPERVISED BY ADULTS." CPSC Docket No. 74-3, Part I, 38-40 (1974).

[57] Commissioner Franklin concurred with the majority that Class C firecrackers do cause serious injury and that the protection of the public health and safety can be adequately served only by keeping them out of the channels of interstate commerce. But Commissioner Franklin dissented from the majority and found that the record did not support .772 grains of powder (50 milligrams) as the basis for an across-the-board standard for nationwide applicability. The primary reason for the creation of the artificial distinction at .772 grains was based on the majority's finding that it must accommodate the religious needs of the Chinese American community. Commissioner Franklin found that the smaller firecrackers or "lady fingers" would not satisfy Chinese-American religious needs. Rather, in her opinion, all Class C firecrackers—both common firecrackers and lady fingers—should be banned with one narrow exception to permit the usage of firecrackers for *bona fide* religious ceremonial purposes. CPSC Docket No. 74-3 (concurring opinion of Barbara Hackman Franklin issued March 4, 1976). Commissioner Pittle dissented from the treatment accorded the banning of firecrackers. The majority concluded that only those firecrackers that contain more than 50 mg. of pyrotechnic composition should be banned. Commissioner Pittle favored a total ban on firecrackers without regard to their powder content. The Commissioner, however, would permit an exception with a state licensing and distribution network analogous to that presently used for distribution of firecrackers for agricultural purposes. CPSC Docket No. 74-3 (concurring and dissenting opinion of Commissioner R. David Pittle issued March 3, 1976).

On June 23, 1977, the Court of Appeals for the District of Columbia circuit remanded the case to the commission for further clarification.[62] The court had technical difficulties with the commission's ban. The court held the commission could not adopt by a 2-2 vote as a final decision what it previously adopted as a tentative 3-2 majority vote. Therefore, there had never been a legal vote elevating the decision to a final order. The court also sought clarification concerning the basis for overturning the administrative law judge's finding that hazards associated with firecrackers containing 1.2 grains or less of explosives may be remedied by labelling rather than imposing a ban.

On a remand the commission formally adopted their 2-2 decision as final by a vote of 3-2[63] and buttressed their reversal of the administrative law judge's conclusion concerning firecrackers with further reasoning.

Recently the commission, in one of its more highly publicized decisions, banned the sale of any children's clothing containing the flame-retardant chemical TRIS.[64] The commission acted in response to petitions filed in federal district court by the Environmental Defense Fund (EDF).[65] Alleging that the flame-retardant chemical TRIS was carcinogenic, EDF sought a total ban on the sale of TRIS-treated wearing apparel.[66]

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[58] The Commission rejected a total ban on firecrackers due to the likelihood of increased illegal trafficking and bootlegging of larger, more dangerous firecrackers. In addition, the commission opined that it would be difficult to administer a possible religious exemption for Americans of oriental descent. Such an exemption could possibly result in widespread unlawful distribution.

[59] 16 C.F.R. § 1507 (1976).

[60] 15 U.S.C. § 1261 (f)(1)(B) (1970).

[61] General labelling requirements must comply with 16 C.F.R. § 1500.121 (1976) unless a firework device requires a special label as set forth in 16 C.F.R. § 1500.14(b)(7) (1976).

[62] *National Society for the Prevention of Blindness, Inc. v. Consumer Product Safety Commission*, No. 76-1495 (D.C. Cir. June 23, 1977).

[63] The commission rejected the administrative law judge's recommended decision insofar as they were applicable to blackpowder firecrackers on the ground that the evidence did not demonstrate these firecrackers to be any safer than flashpowder firecrackers. The 1.2 flashpowder recommendation was rejected because it was not shown to be a common production unit and was based on a single staged demonstration at the hearings. The commission rejected the recommendation on the fusing requirement on the ground that the evidence did not demonstrate that the visibly burning fuse was available or would work in firecrackers. The commission did agree to adopt the administrative law judge's labelling recommendations to the extent that they complied with the statutory labelling requirements of § 2(p) of FHSA and regulations. 42 Fed. Reg. 34873 (1977).

[64] 42 Fed. Reg. 18850 (1977).

[65] *Environmental Defense Fund v. Consumer Product Safety Commission*, No. 770517 (D.D.C. March 1977).

[66] A two year feeding study conducted by the National Cancer Institute (NCI) showed that TRIS caused cancer in test animals even though there were no instances where contact with TRIS had led to cancer in humans.

The commission, based on its own laboratory testing, found that TRIS could be absorbed by children through the skin or by "mouthing" TRIS-treated children's clothing. After a closed session between the staff and the commission, a ban on the sale of all TRIS-treated garments with an authorization for a consumer refund was published in the *Federal Register*.[67] No representatives of the manufacturing, wholesaling, or retailing industry were afforded their procedural safeguards such as advance notice, right to file objections, or right to a public hearing. A federal district judge in South Carolina found that the commission violated the textile industry's right to due process and enjoined the commission from enforcing the ban.[68]

In a separate action the American Apparel Manufacturers Association sought an injunction against the commission's repurchase order requiring apparel manufacturers to bear the entire economic burden of the TRIS ban.[69] On May 3, 1977, Judge Hart gave the commission 10 days to amend the definition of banned hazardous substances to include fabric, yarns, and fiber in cut or uncut form. Thus, fabric and TRIS manufacturers were ordered to share the economic burden of repurchase. The commission voted unanimously to extend the ban.[70]

Industry-wide regulatory ban on TRIS-treated children's sleepwear is presently in a state of limbo. The commission is attempting to impose individual bans upon retail sales of TRIS-treated sleepwear by petitions for injunctive relief in separate enforcement actions against retailers in numerous federal district courts.[71]

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[67] 42 Fed Reg. 18,850 (1977).

[68] *Spring Mills, Inc., v. Consumer Product Safety Commission and Environmental Defense Fund, Inc.*, 434 F. Supp. 416 (D.S.C., 1977). On review, the Fourth Circuit Court of Appeals refused to stay the order. No. 77-1969 and 77-1970, (4th Cir. August 11, 1977).

[69] *American Apparel Manufacturers Association v. Consumer Product Safety Commission*, No. 77-482 (D.D.C. May 3, 1977).

[70] 42 Fed. Reg., 22878 (1977).

[71] The following injunctions against retailers have been brought by the Commission to enjoin the continued sales of TRIS-treated articles of children's wearing apparel.

1. *United States v. F.W. Woolworth Co.*
   CA. 77 Civ. 2437 (S.D. N.Y.)
   Final Consent Order entered May 17, 1977.
2. *United States v. Ayr-Way Stores, Inc.*
   CA. IP 77-336-C (S.D. Ind.)
   Final Consent Order entered June 15, 1977.
3. *United States v. R.H. Macy & Co.*
   CA. 77 Civ. 4124 (S.D. N.Y.)
   Final Consent Order entered November 4, 1977.
4. *United States v. Zayre Corporation*
   CA. C-77-2532-S (D. Mass.)
   Preliminary Injunction issued December 11, 1977.
5. *United States v. Allied Stores Corp.*
   CA. 77 Civ. 4214 (LWP) (S.D. N.Y.)
   Final Consent Order entered November 29, 1977.
6. *United States v. Lamonts Apparel, Inc.*
   CA C-77-624-M (W.D. Wash.)
   Final Consent Order entered August 30, 1977.
7. *United States v. Federated Department Stores*
   CA. C-77-497 (S.D. Ohio)
   Final Consent Order entered August 31, 1977.
8. *United States v. E. B. Mott & Co., Inc.*
   CA. 3-77-1194-F (N.D. Tex.)
   Complaint filed September 2, 1977.

The TRIS controversy is still an enigma to the commission. On February 6, 1978, the commission modified the flammability standard for children's sleepwear.[72] The modifications are aimed at addressing the problem associated with TRIS while maintaining the current level of protection.

Another and perhaps better solution would have been to proceed under Section 2(q)(2) of FHSA.[73] If the commission makes a finding that a substance represents an imminent hazard to the public health, it may by order published in the *Federal Register* give notice of such finding, and thereupon such substance will be deemed to be a "banned hazardous substance" pending completion of a section 701(e) formal rule-making proceeding to determine whether the ban should be made permanent or be dissolved. In the interim a preliminary finding of imminent hazard can be made after the commission holds an oral, adversary-type hearing with an opportunity for the presentation of written submissions. This procedure would at least afford all interested parties an opportunity to be heard by the commission before a proposed temporary ban is promulgated.

More recently, the commission, feeling the heat over the TRIS controversy, decided to issue a public interest finding under section 30(d) of CPSA with respect to free-floating asbestos fiber, contact adhesives, and toys and furniture containing lead paint.[74] The commission chose to regulate these products under section 8 and 9 of CPSA rather than under FHSA, thus opting for informal rule making over formal rule making.[75] In addition, the commission favored enforcement of civil penalties under CPSA.

III. THE POISON PREVENTION PACKAGING ACT

Under PPPA, the commission is authorized to develop special packaging standards for household substances in order to protect children from serious personal injury or illness resulting from handling, using, or ingesting such substances.[76]

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9. *United States v. Montgomery Ward & Co., Inc.*
CA. CV 77-3843-RJK (C.D. Calif.)
Complaint filed October 9, 1977
Preliminary injunction denied January 20, 1978
Awaiting findings, conclusions and order.

Injunction against fabric manufacturers: United States v. Burlington Industries, Collins & Aikman Corporation, Cone Mills Corporation, Dan River, Inc., J. P. Stevens Co., Inc., M. Lowenstein & Sons, Inc., Wortham Textile Mills, Inc., CA. 78 Civ. 461 (EW) (S.D. N.Y.), complaint filed February 1, 1978.

Seizure: *United States v. Articles of Hazardous Substance* (TRIS-treated children's sleepwear), CA 78-23-G (M.D. N.C.), United States App. No. 78-1110 (4th Cir. 1978) Complaint filed and seizure effected on January 18, 1978.

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[72] The amendments for the standards for the flammability of children's sleepwear sizes 0 through 6X (FF 3-71) and 7 through 14 (FF 5-74) are as follows:

Residual Flame Time (RFT) and trim testing: The requirement for RFT would be eliminated and the provisions for trim testing would be changed to permit greater use of fabrics without flame-retardant chemicals.
43 4849 43 Fed. Reg. 4849 (1978).

[73] 15 U.S.C. § 1261(q)(2) (1970).

[74] The commission has authority to administratively issue § 15 CPSA remedies of repair, replacement, or refund to enforce the transferred acts after the issuance of a finding by rule under § 30(d) of CPSA thereof, as amended, "that it is in the public interest to regulate such risk of injury under this Act." See note 33, *supra*.

[75] If the substance or product does not present an imminent hazard, promulgation of a regulatory ban under § 8 and 9 of CPSA by Federal Register notice, written comment, and oral argument is a desirable procedure. CPSA § 8 and 9, 15 U.S.C. §§ 2057, 2058 (Supp. V 1975).

[76] 15 U.S.C. § 1472 (1970).

To date there have been no litigated cases under PPPA for failure to incorporate safety closures on bottles or containers involving potentially poisonous household substances. Since violation of PPPA is a violation of FHSA, enforcement under PPPA is similar to that under FHSA.[77] Under PPPA, the commission uses a procedure similar to that incorporated in FHSA by sending a warning letter to the manufacturer when a violation of PPPA is found. Most of the letters advise the manufacturer to recall the product and to notify retailers not to sell until the violation is corrected. However, under PPPA, there is no repurchase provision covering banned hazardous substances as is mandated under section 15 of FHSA.[78] Nevertheless, at the request of the commission, manufacturers have voluntarily recalled the following products:[79]

Products	*Number of Manufacturers*
aspirin	5
furniture polish	5
sodium and/or potassium hydroxide	5
turpentine	3
kindling and/or illuminating	3
methyl alcohol	13
sulfuric acid	4
prescription drugs	1

IV. THE ADMINISTRATION OF THE FLAMMABLE FABRICS ACT

FFA prohibits the introduction or movement in commerce of any product, fabric, or related material which is so highly flammable as to constitute an unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage.[80] Enforcement of FFA is lodged in CPSC utilizing section 5 of the FTC Act.

Although FFA is a public safety statute, neither it nor the FTC Act provides express authority to require notification, recall, and repurchase of items that do not conform to standards issued under FFA. Those provisions of the FTC Act that are incorporated into FFA provide only for the issuance of cease and desist orders upon a violation of the act.[81]

By contrast, CPSA explicitly contains authority to require the manufacturer to either repair, replace, or refund the purchase price less an allowance for use in the case of substantial product hazards.[82]

Thus, the Commission is presently considering on appeal whether it possesses the legal power to recall products from consumers which fail to meet an applicable standard.[83] The Bureau of Compliance has mainly enforced flammability standards for four products: carpets,[84] mattresses,[85] wearing apparel,[86] and children's sleepwear.[87]

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[77] A household substance which is hazardous under PPPA is defined in § 2(f) of FHSA. PPPA § 2(2), 15 U.S.C. § 1471(2)(A) (1970).

[78] 15 U.S.C. § 1274 (1970).

[79] See note 40, supra. All of these products except drain cleaners with sulfuric acid and sodium and/or potassium hydroxide have been recalled for lacking safety closures.

[80] 15 U.S.C. § 1191 (1970).

[81] 15 U.S.C. § 1194(b) (1970).

[82] 15 U.S.C. § 2064(d)(1)(2)(3) (Supp. V 1975).

The first fully contested litigation involving the enforcement of FFA occurred in *In re Congoleum Industries, Inc.*, which was commenced by FTC before CPSC was established.[88] The FTC's administrative law judge's decision, which this commission affirmed, directed recall of carpet from distributors and retailers for testing but not recall "from the floor" of a consumer. The administrative law judge found that implied authority to recall from distributors and retailers was necessary in order to protect consumers from injury, death, or substantial property damage by fire. However, the administrative law judge held that recall of carpet which had been installed in a consumer's home was impracticable because of the legal and practical problems presented by any order contemplating the taking up of installed carpet.

The commission's decision of July 14, 1975 has been on appeal to the Ninth Circuit. The extent of delay inherent in appellate review is illustrated by the fact that the appeal was finally set down for oral argument on February 9, 1978.

A proposed extension of the *Congoleum* doctrine to include recall of failing carpet from the consumer's floor is now pending in three CPSC cases.[89] The matter arose on appeal from an administrative law judge's ruling that the commission, absent a Section 30(d) CPSA finding,[90] does not possess authority under FFA or the FTC Act to order a recall, repair, or refund of carpet actually installed on the consumer's floor. In his opinion, the administrative law judge noted that FTC failed to obtain authority from Congress to effect consumer recall; that FTC never invoked administrative recall authority on its own initiative in a contested case; and that under the recent FTC Improvement Act,[91] Congress, instead of granting administrative recall authority to FTC, authorized the agency to apply to a federal district court to obtain recall and refund remedies.[92]

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[83] See discussion in note 10, *supra*.

[84] The Standard for Surface Flammability of Carpet and Rugs, FF 1-70, 40 Fed. Reg. 59931 (1975), 16 C.F.R. § 1630 (1976), is commonly referred to as the "pill test." The test method requires eight replicate 9" x 9" carpet specimens. The specimens are dried in an oven and placed in a draft free environment. A flattening frame with a hole four inches in radius is placed on the specimen. A small methenamine tablet is then placed in the center of the hole and ignited. If the flame front burns within one inch of the flattening frame, a specimen fails. If two specimens of the eight tested fail, the sample is considered as failing.

[85] Standard for the Flammability of Mattresses (FF 4-72) as amended 40 Fed. Reg. 59940 (1975), 16 C.F.R. § 1632 (1976).

[86] Standard for the Flammability of Clothing Textiles, 40 Fed. Reg., 59891 (1975), 16 C.F.R. § 1610 (1976).

[87] Standard for the Flammability of Children's Sleepwear sizes 0 through 6X (FF 3-71), 40 Fed. Reg. 59903 (1975), 16 § C.F.R. 1615 (1976). Standard for Flammability of Children's Sleepwear, sizes 7 through 14 (FF 5-74), 40 Fed. Reg. 59917 (1975), 16 C.F.R. § 1616 (1976).

[88] FTC Docket No. 8896, Initial Decision of Chief Administrative Law Judge Daniel H. Hanscom (November 12, 1974).

[89] See note 10, *supra*.

[90] See note 74, *supra*.

[91] Pub. L. No. 94-145, 89 Stat. 801 (1975) (codified at 15 U.S.C. §§ 45, 57a, 57b) (Supp. V 1975).

[92] In the only case where the FTC attempted to issue a consumer refund order involving the fraudulent procurement of a contract, the Ninth Circuit Court of Appeals reversed and the Commission did not seek certiorari. *Heater v. FTC*, 503 F.2d 321 (9th Cir. 1974).

The administrative law judge's conclusion that this commission does not possess the legal power to order recall from the consumer's floor has merit. When Section 3(a) of FFA and Section 5(b) of the FTC Act are read together, they merely provide for the remedy of a cease and desist order against engaging in an unfair method of competition or an unfair or deceptive act or practice. A regulatory agency cannot validly transform language authorizing a cease and desist order into a recall order requiring restitution on the grounds of implicit power to protect consumers.

Additionally, in 1971 the Senate Commerce Committee, reporting on a proposed amendment to the FTCA to empower the Commission to order refunds, stated: "At the present time, cease and desist orders have prospective application only and afford no specific redress to consumers already injured."[93]

In 1975, Congress did grant broad recall powers in Section 206(a) of the FTC Improvement Act to the federal district courts.[94] A condition precedent to obtaining a recall order from the federal district court is the issuance of a prior cease and desist order authorized by Section 5(b) of the FTC Act.[95]

The FTC Improvement Act does not apply prospectively to CPSC. Under the transferred functions provision of Section 30 of CPSA,[96] the commission was subrograted to the position of FTC in enforcing FFA. Any rules, regulations and procedures subsequent to the transfer were to be determined by CPSC rather than FTC. Thus, there appears to be a gap between the commission's regulatory and enforcement powers without the legal power to recall from the consumer.

The commission's only alternative to a congressional amendment is to make the necessary 30(d) finding under CPSA that "it is in the public interest to regulate such risk of injury under this Act."[97] Then the respondent would be subject to the repair, replacement or refund elective remedies provided under CPSA.[98]

The majority of alleged violations of the flammable fabric standard have been settled by consent order in which some manufacturers, apparently not interested in litigating the commission's recall power under FFA, agreed to recall all noncomplying products from distributors, retailers, and consumers. When the recalled product is returned to the manufacturer, the latter can either bring it into compliance with the flammability regulations or destroy it.

Even though it takes both parties to agree upon a remedial action, CPSC appears to be in a superior bargaining position. By urging the manufacturer to enter into a consent agreement in lieu of litigation, violative products are being recalled from the consumer under questionable statutory authority. The manufacturer might, in this instance, be forced to recall violative products when the commission's power to recall is still an unsettled question.

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[93] Pub. L. No. 94-145, 89 Stat. 801, § 206(a) (1975).

[94] S. 3755, 94th Cong., 2nd Sess. (1975).

[95] In the 94th Congress, Senate Bill, S-3755, was proposed to extend the FTC Act, as amended, to CPSC. The effect would be to expressly authorize CPSC to apply the remedies provided to FTC under the more recent FTC Improvement Act. This bill was never passed thus leaving the commission without the legal power to administratively issue a consumer recall, replacement or regund order to enforce FFA by action under § 5(b) of the FTC Act.

[96] 15 U.S.C. § 2079(d) (Supp. V 1975).

[97] 15 U.S.C. § 2079(d) (Supp. V 1975).

[98] 15 U.S.C. § 2064(d)(1)(2)(3) (Supp. V 1975).

The commission has dealt with other cases not involving the recall issue. In three cases the commission dismissed the notices of enforcement due to voluntary action by respondent in immediately withdrawing the dangerously flammable fabric from sale, improper flammability testing, and bankruptcy of respondent.[99] In two other cases, the administrative law judge issued a cease and desist order and recalled cardigan sweatshirts, nylon scarves, and untested mattresses for failing to meet the flammability standard.[100]

All products regulated under FFA are subject to an applicable standard which may prove to be a *per se* limitation. The question remains open whether the existing standards and testing procedures accurately regulate the hazards involved.

In an enforcement case against Ups 'N Downs, Inc., a retailer of cotton tops, the administrative law judge concluded that statistical projections of failure are not enough to prove a flammability case.[101] The staff tested 89 items from various retail outlets and found 26 of them failed the flammability test. None of the samples collected from Ups 'N Downs failed the standard when tested, thereby raising a substantial issue as to whether this retailer did in fact sell any failing playtops. The staff's case largely rested upon a statistical presentation, which indicated that between 13 and 23% of the samples obtained from all of the retail outlets of the importer which were tested failed and, therefore, that it was probable that some percentage of the playtops sold by Ups 'N Downs, Inc., were failing garments. No correlation between the statistical projections of failures and the actual cause of the failures was ever proved. Thus, the administrative law judge refused to issue a cease and desist and recall order since there was insufficient proof that respondents actually sold a flammable garment.

Since violation cases are the easiest to litigate, respondents many times are unnecessarily harrassed. For instance, complaint counsel[102] has brought actions against respondents for failing to prototype test their mattresses and maintain records as required by the standard.[103] They argue that the failure to test mattresses and keep records of test results creates a presumption that the mattresses produced and marketed in violation of the flammability standard present an unreasonable risk to consumers so as to require the manufacturer to cease and desist from manufacturing and recall the mattresses (offering replacement or refunds).

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[99] *In re J. J. Newberry Company*, FTC Docket No. 8849, Initial Decision of Administrative Law Judge Donald R. Moore, (January 22, 1973). *In re Cone Mills Corporation*, FTC Docket No. 8900, Initial Decision of Administrative Law Judge Eldon P. Schrup (August 28, 1973). *In re Esquire Carpet Mills, Inc.*, by order dated June 2, 1975, CPSC returned this case to Administrative Law Judge Ernest G. Barneson. CPSC affirmed the administrative law judge's decision on December 11, 1975. CPSC Docket No. 75-6 (FTC Docket No. 8913). Final Order (December 11, 1975).

[100] *In re Dunck*, FTC Docket No. 8893, CPSC Docket No. 75-4, Initial Decision of Administrative Law Judge David H. Allard (April 23, 1973 and after reopening by the Commission on May 18, 1976). *In re Slumber King Mfg. Corp.*, CPSC Docket No. 75-24 (Jan. 27, 1977).

[101] *In re Ups 'N Downs, Inc.*, CPSC Docket No. 76-3, Initial Decision of Administrative Law Judge Paul N. Pfeiffer issued June 20, 1977.

[102] The Bureau of Compliance complaint counsel is responsible for prosecuting violations under the Acts.

Failure to properly conduct flammability tests, frequently results from the confusion in the mattress industry as to the exact meaning of such terms as "mattress prototype" and "mattress type." In the *National Mattress Company* case, the administrative law judge rebuked the commission's staff for failing to promote voluntary compliance in lieu of an expensive and broad cease order prohibiting the firm from violating not only the testing provisions of the mattress standard charged in the complaint, but any possible violation of FFA[104] in the future, which violation could result in substantial civil penalties. In an innovative decision the administrative law judge issued a limited cease and desist order prohibiting the precise future sampling, prototype, and product testing violations alleged in the complaint and supported by the evidence of record. Once again, enforcement counsel had proposed a remedy of a broad cease and desist order which is far more severe than the hazard which it sought to prevent—a classic case of overkill.

V. ARTICLE III COURTS REACTION TO CPSC ENFORCEMENT ACTIONS

Enforcement counsel has the option under section 12 of CPSA[105] to resort to Article III courts rather than "in-house" administrative hearings. The commission has authorized enforcement counsel to seek court injunctions in numerous cases as a short-cut in lieu of an administrative hearing.

However, the commission has not fared well in the courts. In the TRIS controversy, the District Court for the District of Columbia found that the commission did not go far enough in properly distributing the economic burden among fabric, garment, and TRIS manufacturers.[106] The federal district court in South Carolina enjoined the TRIS ban for lack of procedural safeguards[107] and the judge in the Central District of California refused to issue an injunction because of insufficient proof of carcinogenity.[108] In the case of vinyl chloride the Court of Appeals for the Ninth Circuit found that the commission failed to hold the necessary formal rule making proceeding on the record before promulgating a regulation under FHSA.[109] While the commission was debating whether to commence a section 15 CPSA proceeding involving allegedly hazardous aluminum wire, a federal district court enjoined the commission on jurisdictional grounds, holding that aluminum wire is not a consumer product for use in or about the household but instead a part of the home which is regulated by local ordinances and building codes.[110] On the other hand, the District Court for the District of Columbia[111] found that the commission did have jurisdiction. Both decisions are currently on review in the Third and District of Columbia circuits.

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[103] *In re F&D Associates*, CPSC Docket No. 76-4, settlement (July 9, 1976). *In re Castro* (Bay Area Mattress Co., and Keva Mattress Co.), CPSC Docket No. 75-2. The Commission on January 29, 1976 affirmed the administrative law judge's issuance of a cease and desist order prohibiting the manufacture of untested mattresses in the future. No recall order was issued since there was no evidence that any of the mattresses in the hands of purchasers had failed the mattress standard. *In re Slumber King Mfg. Corp.*, CPSC Docket No. 75-24, Cease and Desist and Recall Order, (January 27, 1977),

[104] *In re National Mattress Company*, CPSC Docket No. 76-9, Initial Decision of Paul N. Pfeiffer (August 26, 1977).

[105] 15 U.S.C. § 2061 (Supp. V 1975).

[106] *American Apparel Manufacturers Association v. Consumer Product Safety Commission*, No. 77-682 (D.D.C. May 3, 1977).

[107] *Spring Mills, Inc., v. Consumer Product Safety Commission and Environmental Defense Fund, Inc.*, 434 F. Supp. 416 (D.S.C. 1977). On review, the Fourth Circuit Court of Appeals refused to stay the order, No. 77-1969 and 77-1970, (4th Cir. August 11, 1977).

[108] *United States v. Montgomery Ward & Company, Inc.*, No. 77-3843-RJK (C.D. Calif. Jan. 20, 1978).

Recently, a federal district court judge invoked the doctrine of exhaustion of administrative remedies where respondent in an FTC action to regulate the official airline guide under the antitrust laws challenged FTC jurisdiction.[112] The judge concluded that the plaintiff failed to show that the statutory mechanism for ultimate appellate review of the challenged agency action is inadequate to protect his rights before he may seek a district court injunction.

This illustrates the reluctance of federal district court judges to hear administrative cases *ab initio*. Why should the court clog their calendars unnecessarily when the agency's own administrative law judge has probably more expertise to handle it and when the administrative process has already begun?

If for example, TRIS or aluminum wire had initially been commenced "in-house" before an administrative law judge instead of resorting to the federal district courts or waiting to be challenged in the district courts, a final administrative decision coupled with the right of appellate review could run its natural course. By circumventing its own administrative process, the commission has prodded different localities into diverse opinions. Thus, the short-cut has become a long-cut.

CONCLUSION

Consumer interest in product safety is of recent vintage. Thus, critics are closely scrutinizing the workings of the commission to see whether it is functioning as Congress intended. Consumer groups are stressing the need for more and better standards, arguing that the commission is not going far enough in regulating unsafe products. Industry takes the opposite view. Manufacturers, distributors, and retailers believe the commission is going too far in regulating and in placing such a heavy economic burden on them. Others contend that the commission is of no purposeful use since there are not many truly hazardous products in the marketplace and that the Commission's approximately 40 million dollar annual budget does not justify policing a few hazardous products.

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[109] See note 44, *supra*.

[110] *Kaiser Aluminum & Chemical Corporation v. Consumer Product Safety Commission*, No. 76-44 (D.Del, March 11, 1977), *appeal pending* No. 77-1874 (3rd Cir.).

[111] *United States v. The Anaconda Company*, No. 77-0024 (D.D.C., June 15, 1977), *appeal pending* No. 77-1628 (D.C. Cir.).

[112] *The Reuben H. Donnelley Corp. v. FTC*, No. 77C2218 (D. Ill. Dec. 20, 1977).

A major criticism directed against the commission is undue delay. Complaint counsel is bringing actions today for violations which occurred three or four years ago. The litigated cases have in many instances raised spurious issues requiring dismissal or minor remedies. Where recall has been ordered, the time lapse between investigation and final decision has been such as to minimize the remedial effects. Only about 15% of products ordered to be recalled have in fact been tendered by consumers. Hopefully, the notice requirements incorporated in the cease and desist orders have adequately warned consumers and prevented a substantial number of injuries and deaths. Until the issue of recall from consumers in FFA enforcement actions is resolved by the commission[113] and ultimately by the courts,[114] litigation under this act appears to be at a standstill.

The Commission is moving rapidly toward the promulgation of rules of practice in expedited proceedings to process administrative civil liability cases including a number involving failure to timely report the existence of a substantial product hazard. This would be a step toward remedying delay.

Another weak link in the commission's performance is the lack of a sufficient number of standards. A fabric, related material, or product not subject to an applicable standard may go unregulated under FFA. The consumer's only redress then is to petition the commission to institute an investigation and research the development of a new standard. This has proved to be extremely time-consuming and costly. In contrast, even though a product may not be subject to an applicable standard under CPSA, complaint counsel may bring a section 15 administrative action if a substantial product hazard exists.[115] The commission, instead of promulgating safety standards has the burden of proving, based upon the substantial evidence of the record taken as a whole, that a substantial product hazard exists. Thus, a consumer receives greater immediate protection under CPSA than FFA if an unsafe product has not been subjected to a standard.

The legislative mandate to protect public health and safety would most certainly be enhanced by combining the various remedial powers under the five acts. The commission cannot afford to dismiss a case after two years and a full administrative hearing upon a finding that it was issued under the wrong law.[116] CPSA and transferred acts are not mutually exclusive. Like all new agencies, the commission is experiencing growing pains. As a safety regulator the commission could best serve the needs of industry and consumer alike by promulgating regulations and taking administrative enforcement action under the most modern CPSA. The courts primarily serve the review function and were not intended to supersede the large and expert-staffed regulatory agency in the initial adjudicatory stage.

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[113] See note 10, *supra*.

[114] *In re Congoleum Industries, Inc.*, FTC Docket No. 8896 (1974); *appeal pending* No. 75-3112 (9th Cir. Feb. 18, 1976).

[115] 15 U.S.C. § 2064(c) (Supp. V 1975).

[116] CPSC Docket No. 75-16, Appeal from Initial Decision (July 20, 1976).

Dun's
Review

A RECORD YEAR FOR RECALLS

The government is getting tougher on product safety, and liability suit awards are soaring. One expert sees the number of product recalls growing at a 10%-to-15% annual clip.

At the recent *Financial Follies*, an annual black-tie spoof of business put on by the New York Financial Writers' Association, the opening number depicted Chairmen Henry Ford of Ford Motor Co. and Richard A. Riley of Firestone Tire & Rubber Co. singing (to the tune of *Feelings*): "Recalls! They're bugging us with recalls . . ."

It is nothing for businessmen to sing about, for as Jimmy Durante might phrase it, industry ain't seen nothing yet.

Last year, a record total of more than 50 million products—from foods, drugs and cosmetics to autos, appliances and toys—were recalled by their manufacturers, either voluntarily or under pressure from one of the four major government agencies empowered to police the marketplace for dangerously defective products. (Products that are defective but not hazardous are not recalled.) And the prospect is for an even bigger recall year in 1979. One expert predicts that over the next five years the number of recalls will not only grow at an annual rate of 10%-to-15%, but that all automakers and perhaps half the manufacturers of TV sets and electric appliances will recall at least some of their products.

Management Migraine

As it is, next to profit, recall is probably the most spoken six-letter word in executive suites nowadays. The Conference Board reports that a significant number of the 50,000 information requests it receives from business each year now deal with recalls, though some companies euphemistically call them "distribution in reverse" or "strategic withdrawal." By any name, the complex and costly process of bringing a defective product back to the plant for repair or replacement is now a throbbing management migraine, from which no industry can see any relief. How bad is it? Says E. Patrick McGuire, a project director at The Conference Board: "If you're a major manufacturer, you know you're going to get a recall."

The company that receives a dreaded recall notice from a government agency also knows that it is bad news. For the procedure, which costs the consumer nothing but the cost of shipping, can be forbiddingly expensive for the manufacturer. Depending upon the product, how widely it is distributed and the extent of the correction, the bill can run from thousands of dollars into the tens of millions.

To fix the pollution-control systems on 270,000 of its 1976-model cars, American Motors Corp. figures it will spend around $3 million—including close to $40,000 just for first-class postage to notify the car owners. For Firestone, the cost of replacing 7.5 million steel-belted radial tires in its notorious recall case, in which 41 deaths and 65 injuries were allegedly connected with the tires, may run upwards of $135 million after taxes—more than the company's net income in fiscal 1977. It could be worse, however. When the presence of botulism showed up in Bon Vivant mushroom soup several years ago, the financial and public relations trauma of the subsequent recall proved so devastating for its maker that the company went bankrupt.

To the consumer, recalls have become synonymous with cars, which accounted for a huge share of all the products called back by manufacturers in every industry last year (*table, page 31*). But the automakers have no corner on problem-prone products. The roster of recalled products in 1978 alone includes a smoke detector that could overheat and start a fire; chocolate lollipops containing metal filings; a baseball pitching machine with a propensity for hitting people instead of bats, even in the "off" position; beetle-infested Easter baskets; a rifle that may fire without anyone pulling the trigger; ping-pong tables prone to collapse; a cookbook containing a recipe for "silky caramel slices" that omitted an ingredient (water) and thus might cause a crockery cooker to explode and another book with a recipe calling for a variety of rhubarb that could be poisonous.

Fire Drills

Not unwisely, a number of companies not yet hit with recalls are gearing up for a procedure that is becoming practically inevitable by conducting mock recall exercises. As part of its annual plant audit system, Pillsbury Co. selects a product at random and launches a "trace" to find out specifically where an entire production run may be in the distribution pipeline. "We don't call it a recall," cautions Vice President John Haaland. "That's a federal word." At General Mills, which claims that it has never had a food recall, a similar "dry run" is conducted periodically, but plant and distribution personnel are never told if the operation is real or merely a fire drill. Says Warren Schweicke, director of quality control of the consumer foods group: "I hope we never have to use the procedure for real."

He may be whistling in the dark. According to The Conference Board's McGuire, who monitors the action in product safety, the inevitability of mounting recalls is due to "a confluence of several factors in an equation that guaran-

Emergency recall: The FDA once sent sound trucks through Philadelphia streets, warning of tainted fish

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Despite the proliferation of recalls, Made-in-America products are safer and of better quality than goods produced five years ago, according to one authority on safety.

tees more recalls." Products are becoming more complex, government regulations more encompassing and confusing and jury awards in product liability cases more and more generous. (*Item:* a California jury recently awarded a staggering $125 million to a youth who was severely burned in a Ford Pinto.) As a result, says McGuire, manufacturers in every industry are becoming increasingly defensive about products whose performance and safety may only be suspect, let alone demonstrably dangerous. They would rather initiate a voluntary recall than risk even costlier liability suits, with all their attendant bad publicity.

Recall City

But that is just prologue to the enormous problems of carrying out a recall. Manufacturers must put aside public relations considerations and broadcast the fact that a defect exists in a product to a wide public, including shippers, distributors, wholesalers, retail outlets and the ultimate consumer. The procedure is not only difficult, but it can be dramatic. When the Food and Drug Administration discovered several years ago that a shipment of flounder fillets in Philadelphia was contaminated and posed an immediate health hazard, it sent sound trucks throughout the city streets, blaring a warning about the tainted fish.

Although no industry can boast zero defects in its products, Detroit especially is beginning to resemble Recall City. Last year, the automakers processed more than 265 different safety and emission-related recalls involving about 14 million cars. The plight of the car manufacturers was dramatized recently when a Hicksville, Long Island, housewife telephoned her Ford dealer's service department to arrange for an appointment to correct a reported defect in a Ford product. Asked the harried service manager: "Which one?"

In the great auto recall rally, there is no manufacturer that does not have several entries. Even regal Rolls-Royce has not escaped the recall rolls. The haughty British car builder, which never admits that its autos can break down but allows that occasionally they may "fail to proceed," is recalling 2,000 of the most expensive cars ever built. To correct a defect in their cruise controls, Rolls-Royce has called in all the $50,000-Silver Shadows, $80,000-Corniche convertibles and $92,000-Camargues it produced last year.

Yet no automaker has been more wracked by recall problems than Ford. Following nasty publicity involving the potentially hazardous positioning of the gas tank in its early model Pintos, Ford recently undertook a massive recall of some 1.5 million of the cars manufactured between 1971 and 1976. Assuming a 100% recall return (most auto recalls generate a return of less than half that), the job could conceivably cost Ford as much as $40 million.

Even that tab could prove to be comparative small change, however, if the National Highway Traffic Safety Administration rules that enough Ford C6 and FMX transmissions made since 1970 tend to slip into reverse spontaneously that a recall is merited. The company steadfastly maintains that it can find no defect in the transmissions. But a contrary finding by NHTSA could result in a recall of as many as 10 million cars at a cost that Ford cannot begin to estimate. Says Herbert Misch, vice president of environmental and safety engineering: "How can we estimate the cost if we haven't been able to identify the defect?"

At first glance, the burgeoning number of product recalls suggests that U.S. industry, which once prided itself on quality and craftsmanship, is becoming a *shlock* shop of shoddy merchandise. But as Conference Board safety expert Pat McGuire puts it: "Nothing could be further from the truth. U.S. products are generally safer and of better quality than five years ago."

The fact is that every product unit withdrawn from the market in a recall is not necessarily defective. To find a few suspected faulty ones, manufacturers must call in an entire production run. An auto company, for example, may have to recall a run of 100,000 cars just to locate 15,000 defective ones. When Chrysler Corp. recently called back 1.3 million Dodge Aspens and Plymouth Volares to check out reported problems in their front-end suspensions, it identified only 13,000—just 1%—as defective. Unfortunately, consumers assume that every apple in a barrel of recalls is rotten.

Even the regulatory agencies, which at best enjoy an adversary relationship with the manufacturers they monitor, insist that no negative implications about the quality of Made-in-America goods should be drawn from the record number of recalls. The reason recalls are on the rise, says Robert Hellmuth, chief of NHTSA's defects evaluation division, is that the agencies have grown mightily since 1973 with "more people, testing labs and complaint-reporting resources. So we're able to find more problems." Too, the trend to commonality of parts, especially in the auto industry, means that a fault in one model run may also turn up in another. Consequently, instead of a 500,000-unit recall, says Hellmuth, "you've got maybe 5 million cars to check out."

A case in point is Ford, which happens to have had more emission-related recalls than any other automaker since 1973 (nearly 5 million vehicles versus only 818,000 for GM). But as Morton Cohen, acting chief of the Environmental Protection Agency's mobile source enforcement division, points out: "Ford also has the largest number of voluntary recalls. Hence, you might say that Ford has been more diligent about emission defects than the other makers." Says one Ford executive: "That's the only decent thing those guys have ever said about us."

For all their recent notoriety, product recalls are as old as commerce, and then some. Historian Wallace F. Janssen of the Food and Drug Administration suggests that the earliest example of a recall can be found in the sixth chapter of *Genesis*, which, as he interprets it, tells how "the Lord saw that his most important product had become corrupted, and took steps to recall all the contaminated lot—but not the family of the good man Noah." Less spectacularly, the first recorded recall in the U.S. was initiated back in 1903 by Packard ("Footnote," *page 117*).

The Government's Business

Yet early callbacks of everything from cars to Fletcher's Castoria were what the regulatory agencies call "silent" recalls. They were undertaken by manufacturers who considered the actions nobody's business but their own. What happened to change that was a flurry of legislation, beginning with the Food, Drug and Cosmetics Act of 1938, which made potentially dangerous products the government's business as well. Dealing with flammable fabrics, poison prevention packaging, the labeling of hazardous substances and mandatory inside latches on refrigerator doors, the laws empowered federal agencies to police industry for violations of safety standards, and further gave them teeth to force compliance. They also led to the creation of new agencies with jurisdiction over specific industries.

The four major watchdog agencies with powers of recall, and how they approach their task:

- **The Food and Drug Administration,** oldest of the regulators in the consumer safety field, monitors the introduction into interstate commerce of misbranded or adulterated foods, drugs and cosmetics. Currently led by Commissioner Donald Kennedy, the FDA can seize unsafe

RECALL ROLL CALL

Apart from the almost total recall of Detroit's automotive products, scarcely an industry was not affected by recall action in 1978. Herewith a roster of the year's representative recalls.

Product	Manufacturer	Units Recalled
Breakfast bars	Carnation Co.	14.1 million
Water Wiggle toys	Wham-O Mfg. Co.	2.5 million
Riviton construction toys	Parker Brothers	900,000
Stuffed animals	Knickerbocker Toy Co.	500,000
Extension cords	Black & Decker Mfg. Co.	200,000
Rifles	Remington Arms Co.	200,000
Smoke detectors	Pittway Corp.	115,000
Skin creams	Avon Products	104,000
Slide projectors	Eastman Kodak Co.	100,000
Rock polishers	Martin Yale Industries	50,000
Mayonnaise	Kraftco	48,000
Ping pong tables	Sears, Roebuck & Co.	38,000
Refrigerator defrosters	Chadwick-Miller Inc.	23,600
Diet supplements	Peerpark Corp.	12,500
Hair relaxers	Revlon, Inc.	11,000
Sunlamps	General Electric Co.	9,000
Stepladders	Sears, Roebuck & Co.	8,000
Baseball pitching machines	Master Pitching Machines, Inc.	7,500
Stuffing mixes	Stop and Shop Inc.	7,400
Woman's Day Crockery Cuisine	Random House	3,000

THE POWERS OF TOTAL RECALL

Although 90% of all product recalls are considered "voluntary" actions by manufacturers, most are "influenced" by the four major federal agencies empowered to monitor products for dangerous defects. Their growing influence over the past five years is seen below.

Agency	Recall Campaigns		Product Units Recalled	
	1973	1978	1973	1978
Food and Drug Administration	1,153	1,112	N.A.	N.A.
National Highway Traffic Safety Administration	251	241	7,001,000	8,470,000
Environmental Protection Agency	11	29	87,750	5,328,182
Consumer Products Safety Commission	3	128	49,999	15,972,380

or contaminated products or obtain a court injunction to halt their distribution. But according to historian Janssen, "The trend is definitely toward preventive, rather than punitive, regulations. We use the voluntary recall more than court-enforced seizures because it is quicker and less expensive to administer. Also, firms are under great pressure to comply when we request a voluntary recall. Refusal is pretty bad public relations, you see."

As the agency with the longest recall experience, FDA puts most of its thrust where the priorities are. "If it's just a misprint on a label, we usually don't bother with it," explains Gary Dykstra of the compliance section. "But if it's a hazard to health, we go all out." Although the agency deals with one of two Class I critically-dangerous-product situations a year, indicating evidence of an imminent health hazard, most of its recalls fall in the Class III variety: products that violate certain regulations, but pose no threat to health (example: insects in a Thanksgiving stuffing mix). The agency is also moving toward more active company involvement in recalls. Under previous FDA procedures, the company was responsible for the recall, but not for checking on the recall's effectiveness. Now, says William Bryant, the agency's emergency operations coordinator, "We're saying that the complete recall responsibility lies with the firm."

- **The National Highway Traffic Safety Administration,** set up in 1966, is authorized to compel an auto manufacturer to conduct a defect notification campaign if the agency discovers, through testing or overwhelming consumer complaints, the existence of a defect. Headed by Administrator Joan Claybrook, NHTSA (pronounced *nitza* in Washington bureaucrateze) has become such a powerful force in Detroit that an "initial determination letter" from the agency advising a manufacturer of a defect almost invariably results in a "voluntary" recall.

Unreasonable Risk

Empowered to levy a top fine of $800,000 for noncompliance (which it was mulling slapping against Firestone last month), NHTSA has had to go to court only six times over contested recalls—and it won all six cases. Says defects evaluation chief Hellmuth: "We only go to court over what we consider to be an unreasonable risk of accident, injury or death." The agency claims to be fully sensitive to the enormous costs of auto recalls, but insists that none of its determinations is frivolous. As Hellmuth puts it, "We're merely fulfilling our mandate from Congress. Where real safety is involved, with people being incinerated in unsafe cars, how can we worry about

Anatomy of a Recall

It may begin with a letter from an irate consumer to the company that made the lemon or with an angry phone call to a government agency hotline. It can start with complaints from dealers about an unusual number of returns from customers, in mounting accident reports or significant increases in liability suits. Manufacturers themselves may alert the proper agency to a defect in a product. If checking and testing shows it to be potentially hazardous, the result can be a product recall.

In making that final determination, each of the watchdog agencies that can compel a company to recall or replace a dangerously defective product—whether it is a car or a candy bar—has its own procedures. The Environmental Protection Agency, for one, routinely tests 2,500 autos a year for possible emission-related problems at agency shops in six cities. (It borrows the cars from individual motorists, who are compensated with a $50 U.S. savings bond, an engine tune-up and a full tank of gas.) But no agency is more thorough in evaluating a recall than the National Highway Traffic Safety Administration, whose concern is automotive hazards. Indeed, some consumer protection groups contend that it is too thorough.

As part of its data-gathering apparatus, NHTSA relies heavily on more than 5,000 letters it receives each month from car owners and as many as 500 calls a day that flood into its national Hotline (800/424-9393). More than 400,000 consumer complaints about cars have already been fed into the agency's computer, which is programmed to spot trends.

Complaints about a particular car or component are transmitted to NHTSA's engineering analysis group. Cars with suspected defects are then obtained and tested in the agency's specially equipped shop in East Liberty, Ohio.

If a defect is detected, an engineering analysis report recommending a recall investigation is put before a defects review panel, which must decide whether the case is serious enough to pursue. If so, the manufacturer is informed that an investigation is underway and must respond to a forty-question "shopping list" requesting specific information on the car and its reported defect.

Should the panel conclude that evidence of a dangerous defect is overwhelming, an "initial determination letter" from the enforcement division is dispatched to the manufacturer together with a copy of the report, which can be six inches thick. The automaker has the right to refute its findings in a NHTSA hearing. If it loses there, the next step is a "final determination letter" signed by NHTSA Commissioner Joan Claybrook, ordering the company to correct the problem. In other words: recall!

Most manufacturers are quick to comply and hence may claim, with full NHTSA approval, that they are conducting a "voluntary" recall. Yet how many recalls might be initiated without agency prodding is anybody's guess. Nevertheless, the problems of compliance are formidable. The company must inform all owners of the vehicle in a first-class postage letter that the defect exists and can pose a danger. Since cars change hands frequently, the maker must search dealer files and those of state motor-vehicle bureaus to find current owners.

To affect a "proper" correction of the defect, the company is also responsible for supplying dealer service shops with sufficient supplies of necessary parts. Though free to the car owner, recall repairs are billed by the dealer to the manufacturer and can run as much as $20 per hour per car—and may well involve millions of cars.

But that is not the end of the affair. Under NHTSA regulations, the company is also charged with following through on the recall. It must file completion reports with NHTSA every quarter for six quarters. The agency recognizes that, depending upon the severity of the defect, not every motorist relishes the inconvenience of running his car over to the dealer. But if the completion rate is unusually low (and it generally runs around 50% to 60% for late model cars and as little as 10% for old ones), NHTSA may examine the manufacturer's procedures. If the agency finds them unsatisfactory, it can order a "re-recall" campaign.

Although the regulatory lot of the automaker is not a happy one these days, one NHTSA official suggests that there is a silver lining in every car recall: "At least, it gets customers into the dealers' showrooms."

the cost? Somebody's got to eat it."

■ **The Environmental Protection Agency** was set up in 1972 with a special interest in air-pollution emission standards not only for autos but for plants and utilities as well. Under EPA's recall authority, Administrator Douglas Costle can require the manufacturer of any vehicle or engine that does not conform to emission regulations "to submit a plan for remedying the nonconformity" within 45 days.

Sharp Teeth

A watchdog with sharp teeth, EPA categorizes its recalls as "voluntary, influenced and ordered." Unlike NHTSA, which credits auto manufacturers with "voluntary" recalls in 90% of the cases, EPA last year "ordered" recalls for about 25% of the 4.6 million vehicles brought back for correction. "We are not out to 'get' the auto manufacturers," says Morton Cohen. "The recalls we have ordered have not been for minor infractions, but for those far in excess of emission standards. Our job is to clean up cars that are polluting the air and make it so burdensome on manufacturers that they will crank into the manufacturing processes additional costs to prevent recalls." In fact, adds Cohen, EPA encourages manufacturers to "get out in front" and design engines that more than meet minimum emission standards. One example of an out-in-front automaker, according to Cohen: Japan's Datsun.

■ **The Consumer Products Safety Commission** was created in 1972 as the result of landmark legislation in the history of the consumer movement. For the first time, a government body was set up to protect the public, not merely from potentially hazardous products made in one industry, but (with certain exceptions) those made by all industries whose goods are normally used by the consumer. Headed by Commissioner Susan King, CPSC can mandate safety standards and labelling of myriad consumer products and ban or remove any product it finds to be an "imminent" or "substantial" health hazard.

Unlike some agencies, whose own investigations of suspected defective products trigger recalls, virtually all CPSC callbacks originate with manufacturers, who are required to report any safety defects to the agency as soon as they are discovered. As Catherine Cook, director of the product defect correction division puts it, "It is not a violation of any law to make a dangerous product, unless a standard has been violated"—but failure to report a discovered defect to CPSC is unlawful. As a result, of the more than 600 different recalls overseen by CPSC since 1973, only about a dozen had to be ordered by the agency.

Oddly enough, the word recall is nowhere to be found in the legislation. What agencies have is the power to compel companies to correct potentially dangerous defects. The only method that a manufacturer can employ in compliance is to send out a dragnet to get the affected products back. Says the FDA's Gary Dykstra, "We have no legal authority to order a recall. The thing we have in our hip pocket when we request a recall is the veiled threat that if the company's doesn't recall, we'll be forced to go to court for an order to seize the merchandise."

By the same token, none of the laws say anywhere that a manufacturer must correct a defect at no cost to the purchaser. That, too, is a phenomenon of the recall revolution. Costly as the process is, no manufacturer has even been known to levy even a service charge on a recalled product. It is not due to any corporate altruism, but is rather an attempt to redress the poor publicity that is a by-product of any recall. "Manufacturers are afraid of recalls and they hate the public notice," says CPSC's Catherine Cook. "Especially if they've never been involved in a recall before, they think it's the end of the world. That's a shame, because it's not. The fear that companies have of publicity is groundless." Indeed, adds director Cook: "We've had so many recalls that the public hardly notices them any more."

> "We don't expect companies to stand up and say, 'I sinned,'" says one agency official. "They may even come out of it smelling like good guys."

What companies fear most is that sales, not only of the recalled product but of all their branded goods, will suffer if the general public gets wind of a recall. Yet as historian Janssen points out, "It's possible to convert a callback into a goodwill gesture." When Fletcher's Castoria, a children's laxative, returned to dealers' shelves following a celebrated recall for contamination in 1943, sales continued brisk as though nothing had happened. Says Janssen: "Mothers thought as highly of the product as before. They seemed to be impressed by the company's directness and integrity in voluntarily recalling the product."

More recently, when the Corning Glass Works discovered in 1976 that some handles on its model E-1210 Corning Ware coffee percolator tended to come loose because of faulty epoxy, the company went all out to put into operation "a model recall," according to Robert McCleary, manager of consumer affairs. It not only spent about $1 million on point-of-purchase tent cards, urging customers to return the defective pots for a free replacement, but saturated the media with news releases alerting consumers to the defect. In all, Corning got back 105,180 of the 360,500 percolators in dealers' and consumers' hands, a return of about 30%—or nearly double the average for such products. Better still, according to Hal Warner, manager of products information, sales of Corning Ware percolators have actually increased since the recall.

But Corning also got something it never bargained for: a $325,000 fine from CPSC, the biggest penalty ever imposed by the agency, for allegedly failing to fulfill the "timeliness" requirement. CPSC claims that Corning was lax in not alerting the agency to the defect within the prescribed 24 hours. For its part, Corning retorts that it was impossible to make a defect determination in so short a time. And considering that CPSC has since extended the notification period to fifteen days, the glass company not unreasonably contends that it got a bum rap.

Another recent recall that drew the wrath of CPSC was the smoke detector that was itself a fire hazard because of the possible malfunction of a resistor. In a way, muses defect corrections director Catherine Cook, "it was rather funny." Not funny, however, was the $100,000 fine that CPSC slapped on its manufacturer, Pittway Corp., for allegedly failing to report the defect to the agency.

The Language of Recalls

Nevertheless, to hear the agencies tell it, they bend over backwards to make certain that a recall notice does not result in a bad press for the company or, worse, grounds for a liability suit. "The language of a recall notice is very important to manufacturers," CPSC's Cook explains. "They fear anything that can be construed as an admission of guilt." In phrasing a joint news release on a safety recall, for example, the agency—not the company—asserts that the product is a hazard. "We don't expect companies to stand up and say, 'I sinned,'" says Cook. "Certainly, it's no harm to the image of a firm to admit it is being cooperative with the Commission. They may even come out of it smelling like good guys. And that's all right by us as long as the word gets out."

Even so, many companies are extremely touchy about discussing recalls. Firestone has put out the word that it will not comment on any facet of its massive tire recall. And asked about the effect on sales of its Mr. Coffee automatic coffeemaker following a recall of 3.1 million machines in 1977 for defective Teflon-

Consumer protection groups want the government to get a lot tougher on recalls. One critic, claiming that no agency is doing a fabulous job, gives them a grade of only B – .

coated wiring. James Yurak, vice president of sales and marketing of Ohio's North American Systems Inc., curtly replies: "We have filed all the necessary papers with the CPSC. And that's how we prefer to leave the matter."

For that matter, Ford is one company that took a public relations bath last summer when it challenged a NHTSA recall notice with a flight of fanciful statistics. Called upon to recall 150,000 Mercury Capris for repair of a suspected windshield-wiper defect, Ford lawyers went into federal court in Washington to argue that, on the basis of empirical statistical data, motorists driving their Capris to dealers for the repair would run the risk of twenty accidents, whereas only two accidents would be likely to result from the defective wipers. "It was just a case of statisticians talking to each other," grumbles Ford Vice President Herbert Misch. "The whole thing was taken out of context."

Ford's Flap

Still, Ford reaped a whirlwind of poor press from the flap. NHTSA rejected the company's reasoning as "ludicrous" and *The New York Times*, while appreciating "the charm of this line of argument," editorialized: "The ultimate logic of the Ford lawyers' argument will triumph when statistics prove that no driver ought to venture anywhere and there will be no recalls ever again."

Not surprisingly, relations between the auto companies and NHTSA and EPA are proper, but cool. Some manufacturers complain that they are unduly harassed by a recall-happy bureaucracy more concerned with "imposing its will" than correcting defects. Not so, replies EPA's indignant Mort Cohen: "I don't think we are overzealous. But we are extremely cautious when it comes to automotive safety." At NHTSA, Robert Hellmuth points out that his defects-evaluation division is manned by only 35 of the agency's 900 employees. But because it has sparked the recall of 74.2 million vehicles since 1966, he says, "We just seem to catch more hell than anyone else."

Yet for all their growing reach and clout, even the agencies admit that their defect-detection apparatus could stand improvement. Despite the risk of fines for negligent reporting, many small companies and importers shrink from the expense of a recall. Among larger corporations, says Catherine Cook, "foreign manufacturers are at least as good about recalls as the domestic ones because they value their name. But if your name doesn't appear on the product, you're not going to care about conducting the recall." Moreover, while the agencies' punitive powers have improved the rate of defect reporting, Cook complains that "even now we're only hearing about a fraction of the cases that require recall, maybe way less than half—but that's only a guess."

The agencies also get something less than high marks for their efforts from environmentalists and consumer protection groups that would like to see them get a lot tougher. One outspoken critic is Clarence Ditlow, director of the Center for Auto Safety, who does not think "any agency is doing a fabulous job of recalls." As head of the organization founded by Ralph Nader, whose *Unsafe At Any Speed* helped to inspire the creation of NHTSA, Ditlow necessarily speaks as a devil's advocate where the auto agencies are concerned. Says he: "I'd have to say they are working at a B – level."

Critical of NHTSA's reliance on consumer complaints as the basis of many recall investigations (*page 32*), Ditlow also charges that the agency is too slow in launching investigations. He points to the low number of NHTSA investigations during the Nixon years 1973-74 and concludes: "They must have taken a lot of long lunch hours." He acknowledges, however, that "since [Administrator Joan] Claybrook came in, they've improved sharply."

Carl Nash, special assistant to Claybrook, sardonically suggests that the B-grade is "very charitable" of Ditlow and is "certainly higher than he would have given us in the past." Preferring not to comment on the work of NHTSA's previous administration, Nash points out that "under Mrs. Claybrook, we have expanded the definition of a safety-related defect"—for example, a propensity for engine stalling in some Plymouth Volarés. He concedes, however, that "given the resources, I'm sure we could find other cases worthy of recalls." As for the agency's "Hotline" for receiving consumer complaints, which Ditlow denounces as "a real disaster," Nash points out that its twelve operators are frequently overwhelmed by incoming calls, "particularly when a case like the Firestone 500 tires comes up." But the agency is computerizing information so that callers can get prompt answers to their questions about auto recalls.

At the same time, considering that NHTSA no longer has to prove injury from a defect but need only determine the likelihood of one happening, Ditlow thinks the agency lacks aggressiveness. Specifically, he charges NHTSA with dragging its feet over the Ford transmission case now under investigation, which Ditlow claims was sparked by a letter from his organization. He also charges that in replying to NHTSA's requests for information on its transmissions, "Ford stalled for three months on the question of including trucks in its data, and it is still fighting the investigation tooth and nail." Stunned by Ditlow's accusations, Ford's Misch told DUN'S REVIEW: "We are not! He's crazy! We have cooperated fully with the agency and will continue to do so. The only thing we ask is that facts should be separated from allegations."

Stretching the Bounds

The undeniable fact about recalls is that they are bound to increase. Not only are the agencies flexing their muscles more vigorously but, in liability cases, courts are stretching the bounds of normal and intended use, making manufacturers responsible for the use of their products in ways never dreamed of by their designers. *Item*: The housewife who was nearly electrocuted when she put an electric crockery pot inside her tub to heat the bath water. And in California, a woman settled out of court after suing a chemical company because she received a rash while sunbathing nude on a lawn she had just sprayed with its insecticide. Companies are also being burned by absurd rulings by the agencies themselves. Pennsylvania's Standard Novelty Works was nearly forced to call back 100,000 sleds because paint on the runners contained lead. Claiming that "kids don't bite their sleds," President Norman Rosen won a one-year exemption, but has nevertheless switched to using more expensive non-leaded paint.

To guard against recalls, urges The Conference Board's Pat McGuire, companies should "learn a lot more about how their products are used, build safety into everything they make and worry less about styling." Says McGuire: "Nobody ever recalled a product for being ugly."

Meanwhile, the ultimate recall may have surfaced recently when the University of North Carolina called back the 3,100 diplomas it awarded to the class of 1975. It seems that more than 1,000 graduates had complained to the school that the ink on their sheepskins is fading. Which only goes to show the degree to which recalls have become part of the American condition.

—ROBERT LEVY WITH MARK LEVENSON

DEBATE PROPOSITION TWO

RESOLVED THAT: THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR THE REGULATION OF COMMERCIAL ADVERTISING

There can be no doubt that advertising plays an important role in the American economy. As they have for years, advertising expenditures continue to account for over 2 percent of our Gross National Product. On a per capita basis, the United States spends three times as much as the number two-ranked country, West Germany. Yet while few would disagree that advertising has been, and will continue to be, a vital factor in the economic growth of this country, a number of critics say that much of present-day advertising is wasteful, manipulative, and too frequently false, unfair, or deceptive.

The regulation of advertising reflects a conclusion that consumers are for the most part not in a position to protect their own interests, because there are simply too many products for consumers to test for themselves, and the process of testing is too expensive compared to the cost of most products. Furthermore, the regulation of advertising can also have pro-competitive consequences. Misinformation not only deflects consumers from an opportunity to make a choice on the merits of rival products, thereby misallocating economic resources, but misinformation also creates the immediate danger that true invention and innovation will be replaced by spurious advertising campaigns. Similar anticonsumer and anticompetitive effects can occur where all companies in an industry maintain silence with respect to strategic product data, without which consumers cannot make a sensible choice among rival brands.

While most observers agree that some regulation of advertising by the Federal Government is necessary and desirable, many are convinced that it is vitally important that Federal involvement be kept to a minimum. The advertising industry in the United States has a long history of heavy reliance on self-regulation in order to prevent further intervention, however well-intended, by outside parties whose efforts could seriously impair the proper function of advertising without making any significant contribution to the effectiveness of advertising regulation.

The principal Federal agency charged with the responsibility of regulating advertising is the Federal Trade Commission (FTC). The standards the FTC employs in regulating commercial advertising are grounded in its statutory mandate and shaped by the opinions of the courts. Several key cases have been decided by the Supreme Court during the last few years concerning the protection accorded commercial speech under the Constitution's first amendment. These and related matters are discussed in the following articles.

PRIVATE ENTERPRISE AND PUBLIC VALUES

Advertising and Social Responsibility

James W. McKie

Critics who call for more social responsibility in advertising obviously think that something is wrong with it, or at least with some of its manifestations. They are calling for an improvement of business performance in advertising—voluntarily if possible, or by government enforcement if not.

In recent years these criticisms of business advertising have been coming from many points of the compass. They are not all consistent with each other, and economics does not endorse all of them. Insofar as economics has been critical of advertising, it has focused mainly on two issues. One is the effect of advertising on consumer preferences. Economists have debated whether it does in fact have much influence on consumer choices, and if it does, whether business should be more responsible in exercising it and whether the government should regulate advertising if responsibility fails in some essential way. The other is the possibility that advertising may confer monopoly power on the seller.

If that should be the general effect of advertising, hardly anyone would think that voluntary exercise of business responsibility would be an effective remedy; but it is not easy to say what public policy would be called on to do about the problem.

Advertising and the Primacy of Wants

Concerning the first issue, the effect of advertising on preferences, economics has had some difficulty putting it in perspective. The theory of value usually assumes that consumer wants are "given," primary elements which the market economy (or any economic system having consumer welfare as its main purpose) endeavors to satisfy. But advertising, at first glance, seems to turn the system on its head. If preferences—wants—can be altered or (worse!) *created* by advertising, they no longer seem so primary. Instead, they seem to be produced by the very economic process that seeks to satisfy them.

But these appearances seldom survive a second glance. We have to remember that the assumptions of theory are for convenience only: they do not purport to describe the real world. Few economists really believe that consumer preferences are nothing but an output resulting from advertising input, or that advertising can actually create wants independently of the fundamental drives and behavioral propensities of consumers. It may influence them, just as other circumstances of society can influence them; people are not born into the world with their tastes and preferences fully formed. But all that is beyond the reach of the economist. It is the sphere of the sociologist and the developmental psychologist. Human beings enter the field of vision of economics when they appear in the market, the workplace, the queue, the polling booth, the bank, or the welfare office.

Choice and Affluence

What appears to be the responsiveness of consumer behavior to advertising is probably due largely to the cost of information and image-formation in the affluent American economy. It does not mean that producers of goods and services can shape wants and preferences to fit their requirements. Models in the economics textbooks are apt to assume that consumers always know exactly what they want, what goods and services will satisfy their wants and in what degree, where these goods are to be found, and how similar goods differ from each other—all without anyone's having provided them with this information and without experimenting with different combinations.

There may have been a time when the average family's consumption consisted of allocation of a severely limited income among a few staple commodities so as to gratify, as far as possible, a few simple and urgent wants. In a subsistence economy, where the typical consumer must spend most of his income on basic foodstuffs and rudimentary shelter and clothing, he does not need much information on the nature and availability of commodities. There is no point in advertising yams to the Melanesians or rice to Burmese peasants. Advertising develops when goods become so abundant that they must compete for the consumers' attention. The American economy is far beyond the point of meeting a few stable and pressing wants. The increasing effort devoted to marketing and selling is largely due to the advanced level of want satisfaction it has achieved and the great proliferation of means of satisfaction.

From the standpoint of an individual seller of goods, this

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effort is a matter of necessity if he is to hold a position in the market against the competitive selling efforts of his rivals. Success in this struggle depends on the quality and cost of the selling effort as well as on the intrinsic characteristics and cost of the articles sold. The economic environment compels this result.

The consumer forms an intention to buy a product that he has not consumed before largely because of what he is told about it—information and image. Actual consumption tests the want-satisfying capacity of the product. Both the formation of the wish to buy and subsequent satisfaction are necessary. No advertiser can long sustain a profitable market if the preference is fleeting or if it is disappointed by the product. Commercial history is littered with the wreckage of products and services that failed notwithstanding heavy sales promotion and concerted, skillful efforts to manipulate consumer preferences in their favor.

The entire process of sales promotion, in other words, has to be anchored in reality. Advertising may influence tastes, it may reveal preferences and disclose to consumers the existence of goods and services that will satisfy wants, it may persuade consumers to experiment with the unknown or untested qualities of new goods and services, but it is not self-validating.

Economics retains a firm prejudice in favor of the kind of advertising that enables a consumer to satisfy his wants and exercise his preferences more effectively with than without it, with more satisfaction in proportion to costs including the costs of information and search. Most advertising may meet this criterion tolerably well, but not all of it does. The market process is not instantly or fully self-policing. Advertising can deceive, it can form intentionally false images, without "informing" consumers. What ought to be done about that problem is a question to which we will return after considering the other issue of monopoly power. If advertising has the effect of creating monopoly, of course, the consumer might consider some information to be too dearly bought.

Advertising, Competition, and Concentration

To business managers or advertising executives it may seem absurd to ask whether advertising is an agent of competition. They are acutely conscious of the fierce rivalry for sales that is the very essence of large-scale and imaginative advertising of consumer goods. Conventional economics, on the other hand, defines "pure" competition as a market state in which every firm is too small to influence the market individually. Firms are merely price-takers, and (as pointed out earlier) buyers are assumed to be provided already with all the information they need. Selling costs are therefore symptoms of "imperfection." The word is unfortunate; it appears to mean a remediable defect of some sort. But economists seldom show much concern about mere imperfections, or the costs of information, search, and image formation when a market is well furnished with many sellers vying for consumers' purchases. What concerns them is concentration, monopoly, and oligopoly (or a few large sellers) in consumer goods and services.

Does advertising cause economic concentration? Does it create and preserve monopoly? Does it blockade competitive entry and confer market power on oligopolistic firms that can use it to those ends? Does it victimize the consumer by buttressing monopoly prices?

Several economic studies since World War II have advanced the argument that advertising increases industrial concentration, and by inference monopoly. Nicholas Kaldor held this view about the British economy. William Comanor and Thomas Wilson argued that advertising costs produced concentration, entry barriers, and high profits in consumer goods industries in the United States.

If advertising indeed leads to high concentration, it may be because there are economies of scale in advertising itself. Intensive study of this hypothesis has failed to produce any convincing evidence supporting it, or proving that large-scale quantity discounts, for example, television advertising, confer an advantage on large sellers. Nor does advertising seem to generate high brand loyalty that is disproportionate to the selling effort and that persists over time so as to entrench the position of the seller. Consumers do show loyalty to certain brands under certain conditions, but advertising seems not to be the principal agent in creating loyalty or prolonging it.

Consumers do show loyalty to certain brands under certain conditions, but advertising seems not to be the principal agent in creating loyalty or prolonging it

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But the statistical evidence of the relation between advertising and concentration is itself equivocal. Some studies have found a curvilinear relationship between advertising (as a percent of sales) and concentration, with advertising intensity increasing up to some intermediate level of concentration and then leveling out or decreasing. Other statistical investigations have failed to confirm any such relationship. None of these investigations, certainly, shows that advertising is a *cause* of high concentration. Common sense alone would probably lead us to expect the following:

- Pure monopolies or firms that have dominant positions in their markets, when that position rests on technology, the results of past innovation, economies of scale, governmental franchise, or similar factors, will advertise if they can enlarge their markets, and will do some image or public-relations advertising, but will probably advertise less than they would if confronted with large and powerful rivals.
- Oligopolistic firms selling consumer goods and services, especially those marketed in individual packages of small value and repetitive purchase, are likely to show higher ratios of advertising to sales than firms not engaged in

mass distribution or not having close rivals. Firms selling primarily producers' goods to other businesses are likely to prefer other methods of sales promotion to mass-media advertising.

This does not mean that concentrated industries will show a disporportionately higher outlay on advertising than less concentrated ones, *if other things are equal*. A relatively unconcentrated "industry" such as general retailing by department stores or food retailing often shows quite high ratios of advertising to sales because of the necessity of informing consumers continuously about prices and availability. There isn't any way of isolating the effect of advertising on concentration, or even of determining whether concentration has an independent influence on advertising intensity. Our statistics show rich diversity in possible roles for advertising, but little if any predictable relation to monopoly if concentration is a proxy for monopoly.

We are apt to form strong impressions about advertising from television, the most vivid medium for image formation. The large oligopolistic sellers of consumer goods concentrate heavily on TV campaigns, giving the viewer a sense of massive persuasive effort for single brands even though the advertising outlay may be proportionally no greater than that in unconcentrated industries that rely more on other media. The major TV advertisers have come to symbolize advertising itself: proprietary drugs and toiletries, beer, soap and detergents, soft drinks. But there are anomalies: automobile producers are among the biggest spenders, though their advertising-sales ratio is very low, so is A.T.&T., though it is not an oligopolistic seller; so are some food manufacturers, makers of brassieres and of pantyhose, and franchisers of hamburger stands, though their markets are substantially competitive. Local industries such as savings banks and appliance retailers may give the same impression of persistent presence on the tube with a small fraction of the outlay of Proctor & Gamble. To trace the effects of advertising on monopoly in all this is an almost intractable problem.

Entry

Advertising is said to have erected barriers to entry in certain consumer-goods industries. In some industries with heavy advertising outlays, those expenditures are obviously not the main reason for lack of entry. Hence advertising must have other purposes or rationales even in consumer-goods oligopolies. But established product preferences may require a considerable investment in advertising by new entrants if they aim for nationwide mass distribution using mass media for consumer information. (Here, as elsewhere, we should remember that advertising is not the only avenue for sales promotion. Tupperware and Metropolitan Life, McGraw-Hill and Wyeth Pharmaceuticals make large outlays on sales promotion without relying primarily on advertising.)

Though previous writers had cited advertising as a barrier to entry, "product differentiation" as a barrier is best known to economists through the writings of Joe Bain, who observed that "... the advantage to established sellers accruing from buyer preferences for their products as opposed to potential-entrant products is on the average larger and more frequent in occurrence at large values than any other barrier to entry." In a sample of 20 industries surveyed for that study, Bain found that product differentiation alone was responsible for the very high barriers to entry in cigarettes, liquor, and quality fountain pens, and combined with production scale economies to produce extremely high barriers in automobiles, tractors, and typewriters.

BUMPH
BUMPH

Photo by [illegible] Wood

That was in the 1950s. Those examples, however, looked at from the 1970s, warn us about drawing final conclusions on advertising as a buttress of monopoly power. The liquor industry has been heavily battered by the seemingly autonomous shift of consumer tastes toward vodka and wine, and by several sales-promotion campaigns by the dominant distillers that bombed out. The quality fountain pen industry has practically ceased to exist, not so much entered as annihilated by ball points and disposable fiber-tip pens. Cigarettes are still going strong, but since 1971 without the benefit of the most effective medium of mass advertising; before that the industry had been shaken up rather severely by the filter-tip revolution. Automobiles are still oligopolistic, but the share of imports is now over 20 percent; Volkswagen and Mercedes, Toyota and Datsun somehow were able to locate and tap consumer preferences that the "established" sellers didn't know existed. Several of the apparently leading typewriter manufacturers in the 1950s are now hanging on by their fingernails, while foreign suppliers like Adler and Olivetti have not only entered but engulfed them, and a big firm from outside the industry (IBM) has steadily enlarged its share. I don't know what has happened to tractors, but I doubt whether advertising has had any effect on product preferences or on recent events in the industry.

There are probably more anecdotal histories of products in oligopolistic industries in which advertising assisted the entrant than in which it enabled the previously marketed products to exclude entry. Toyota and Datsun, for example, entered the American market on a wave of market promotion which informed American consumers of their existence and formed the first images of the product. One may doubt whether this advertising would have had to be any less voluminous and extensive to achieve its purpose even if the "established" auto manufacturers had been previously advertising their cars at, say, half of their actual level. Nor did the advertising of the latter attempt any backlash or retaliation, which is always a foolish tactic. At most, the "background noise" of demands on the consumer's attention might have been due in part to advertising, but that relates to products and services in general, not to a particular industry, and reflects affluence and diversity of choice rather than monopoly. Given that circumstance, entry into a market with advertising is easier than entry into a market without advertising.

We have not seen any persuasive evidence that advertising creates or protects monopoly in general

Public Policy and Private Responsibility

If "monopoly" in its several manifestations were really an important result of advertising, there would be little point in invoking "social responsibility" as a remedy or palliative. Those who have claimed to see a menace of monopoly in advertising have suggested various governmental policies for dealing with it: a progressive tax on advertising, strict policing of media to prevent rate discrimination favoring the large advertiser, periodic reversion of brand names to the public domain, etc. But since we have not seen any persuasive evidence that advertising creates or protects monopoly in general, we need not give our attention to general policies of that nature. The point is mentioned here only because many critics of advertising and/or monopoly habitually confuse the issue, seeming to be under the impression that policies or campaigns to foster "truth" in advertising are also antimonopoly policies. To be sure, anything that improves the quality of information is likely to improve the quality of competition, and competition itself can act as a check on fraud by individual sellers. But policies (public or private) to improve the quality of advertising should not be confused with an assault on business monopoly nor taken as a tacit assertion that such monopoly is a principal effect of advertising.

If advertising content (information and image) rather than monopoly is our principal concern, should that concern be expressed primarily as "coercive" government policy or as "voluntary" social responsibility to correct whatever should and can be corrected? Observers of the regulatory process at work know that it does not usually involve pure coercion. Regulation works best when there is voluntary cooperation with it; most regulation is unenforceable in our society without cooperation. Responsibility, in fact, has been defined as "obedience to the unenforceable." Conversely, the same pressures of public opinion and affected interests which lead to regulation may in the first place cause businesses to adopt rules and principles "voluntarily." A broad spectrum of possible combinations runs between the poles of pure coercion and pure inner-directed voluntary action. It is partly a question of what mechanisms are most effective in achieving goals. In recent years, obviously, the public has tended to favor more regulation, and business has had to consider more self-policing to forestall still more controls.

When a firm adopts certain policies in the name of "social responsibility," the conventional interpretation is that it is doing something different from what it would do if it pursued short-run profits with single-minded concentration. Firms that do the latter are not necessarily behaving unethically; they can observe the usual canons of probity, honesty, and candor while maximizing profits. The "responsible" firm goes beyond a common ethical ground to something else: recognizing the indirect consequences of its actions, taking account of the external benefits to the circumambient community when it behaves in certain ways, and perceiving a long-run benefit to itself as well as to other agencies when it contributes to the improvement of the social environment. Such a firm is not motivated solely by the quest for long-run profits, but it is not necessarily indifferent to the reflexive long-run benefits of socially responsible behavior.

Unfortunately, the benefits—both internal, to the firm, and external, to society—are not all measurable. If a firm producing a branded consumer good is trying to decide how much information to disclose to the consumer, and in what medium, and in what style or transmitted with what images, it will soon discover that the apparent marginal benefit of more meticulous accuracy and more voluminous facts diminishes rather rapidly, as consumers' resistance to information increases. The marginal private costs of providing more complete facts tend to rise, both in direct expense and in foregone opportunities for image-making. The firm probably won't push the campaign beyond the point where the incremental cost exceeds its estimate of incremental benefit; but there is no way of knowing whether all of the costs and benefits to society have been incorporated into the decision. Variations in style and taste, obviously, would be very difficult to include, yet much of the shouting is about those very attributes of advertising.

Everything that makes a "socially optimum" advertising policy difficult for the responsible firm would also create difficulties for government regulation

Does this mean that the government has to take over the job of policing *in toto*, as the government frequently has to do when there are large external effects of private-firm decisions? I doubt it. Everything that makes a "socially optimum" advertising policy difficult for the responsible firm would also create difficulties for government regulation. The problem is not the same as in, say, environmental pollution. The government has its best opportunity for an unequivocal contribution in high-risk situations, where lack of consumer protection has a high probability of serious injury. In addition, it may be able to deal effectively with the problem of hit-and-run business with misleading advertising, though the Better Business Bureaus have also made contributions toward lessening that problem.

Both the business community and the government seem to be aware that the benefits curve is shifting. Consumers are valuing information more highly, assimilating it better, and showing greater awareness in judging the accuracy of factual content.

Regulation of Advertising Conduct

Though regulatory policy does not always mirror public opinion exactly, the principal thrusts of policy usually indicate what the public is concerned about. At present the principal ones appear to be: (1) to require advertisers to provide information when its absence would greatly harm the buyer; (2) to prohibit unfair attacks or comparisons that injure competitors; and (3) to protect the consumer from serious harm when he cannot protect himself.

These are worthy goals of policy, but a misdirected or excessive enforcement can produce bad results. Overemphasis on information can lead to information overload; academics know only too well that people resist information, beyond a point. At another extreme it leads to a preoccupation with "truth" as a metaphysical imperative. Some advertising content is "information" only in the McLuhanesque sense of transmission of images. If "truth" is used as a principle of exclusion, to prohibit transmission of what is not rigorously factual, it would put not only advertising but education out of business. Over-concern with injury to competitors can lead to quietism and blunt the effectiveness of competition. Excessive concern with consumer protection against misinformation can lead to a policy of saving consumers from their own folly or monitoring the wholesomeness of their wants.

Examples of all of these excesses of regulation are easy to find. So are examples of excessive preoccupation with minutiae (remember the sandpaper-shaving scandal) which serves no purpose other than to entertain the critics of government regulation. Nevertheless, the fact that Big Brother is watching has certainly had some effect in discouraging fraudulent and deliberately deceptive advertising which could do real harm to the public. Though most advertisers would not take that path even in the absence of regulation, the exceptions would inevitably turn up; some get through the chinks of regulation even now.

The Limits of Economics

Many of the questions addressed by either regulation or a search for greater social responsibility are not questions to which economics can make a useful contribution. If costs and benefits cannot be compared, or if some structural determining factor is under consideration, economics becomes more or less a spectator. For example, one of the leading questions at present is advertising directed at children. It is a critically important question for some industries such as ready-to-eat breakfast cereals. Economics considers the "household" as the unit that makes consumption decisions; protection of children in view of their credulity and lack of integrative perceptions, or protection of parents against children's demands created by advertising, are matters that do not concern it directly. At most we can call for better information on, say, the amount of sugar in the food and its effects on nutritional balance and dental health, as necessary data for cost benefits analysis. (I hasten to add that advertising directed to children *does* concern economists as parents and citizens.)

But, of course, society never has regarded economic wants registered on the market as a decisive test of welfare in all cases; we would not have laws against narcotics if it did. One hopes that this particular problem of advertising to children can be largely controlled by voluntary social responsibility, since it seems an unpromising arena for regulatory intervention.

There is also the question of taste. I could wish for fewer deodorant ads, for less deification of deceased rock singers in order to peddle their records, for fewer episodes of couples murmuring breathily to each other about cheesecake or coffee, for less machismo in automobile, tire, and beer ads, fewer appearances by Harry the Idiot and Madge the Sibyl, for less rapid appropriation of every new popular phrase, style, or attitude by the advertising fraternity, and above all for fewer appealing toddlers cunningly lisping commercials for products to be consumed by adults. But in saying that, I have taken off the economist's hat and joined the general public, whose tastes are not all necessarily the same as mine. If enough voices proclaim the same message, of course, business will sooner or later respond to it, or else government will transmit the message.☐

READINGS SUGGESTED BY THE AUTHOR

Ornstein, Stanley J. *Industrial Concentration and Advertising Intensity*. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1977.

Posner, Richard A. *Regulation of Advertising by the FTC*. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1973.

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Advertising and Information

Roger M. Swagler

Toward A Consumer Perspective

A Consumer Viewpoint

Regardless of who you are or where you happen to be as you read this, you have almost certainly been exposed to some kind of advertising today. In the last chapter I spoke of ways in which the consumer can seek out information, but with advertising, the situation is reversed; it seeks you out, coming into your home over the television and radio and in newspapers and magazines. Advertising is an integral part of American life, and billions of dollars are spent each year to ensure that it stays that way. However, despite such massive expenditures, it isn't at all clear what advertising does *for* or *to* consumers. It is clear that all those dollars spent on advertising haven't fulfilled the consumer's need to know about products. There is evidence, in fact, that the opposite is sometimes true; advertising may confuse consumers and in some cases even mislead them.

The irony of this situation can be traced to basic differences in how advertising's function is perceived. Thus far we haven't spoken of information in terms of telling consumers what they ought to do. We have treated information as impartial evidence that consumers evaluate as they make independent judgments. The intended outcome is a purchase that will promote greater satisfaction; presumably, informative advertising would embody these same elements.

At this point, a conflict arises because advertising intends to sell a particular product. It follows that the function of the ad must be

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to persuade the individual to buy the product. Thus, persuasion replaces impartial evaluation and any persuasive technique that works will be employed. Success is measured in terms of increased sales, and any ad that boosts sales is by definition good. If an ad for Scrubbo Cleanser shows a celebrity extolling its virtues and that gimmick happens to sell Scrubbo, that's all that matters.

There's the rub, the difference in perception mentioned above. Information is meant to provide consumers with a better basis for making independent decisions; advertising is meant to persuade consumers to buy a product. Advertisers are interested in informing the public only if that information will help sell the product. That is why most of what is written about the subject is of little or no value to the student inquiring about advertising from the consumer's point of view. Advertising has been analyzed mainly from the seller's perspective, which views the consumer as someone to be attracted (some would say *manipulated*) rather than someone to be given information.

Dollars and Sense

This raises an obvious question: Should advertising be asked to perform an information function? In answering that question, remember that while information can be gotten to consumers more cheaply than it is now, someone still has to pay the cost of getting it there. Two possibilities suggest themselves: government and business. The government reduces information costs to consumers by forcing businesses to disclose key facts, establishing standards, or providing information directly. The costs are then either forced back on business or paid out of tax monies. If government bears the costs directly, it is ultimately the consumer as taxpayer who shoulders the burden. This may be a more efficient approach, but information costs have only been reduced, not escaped.

If business is forced to bear the cost of providing information to the consumer, this cost, like any other cost of production, would be reflected in the final price of the product. The degree to which this price increase would be passed along to the consumer depends on the degree of competition in the market.* In most cases, however, the consumer will end up paying some, if not all, of the added costs through higher product prices. Again it is the consumer who ultimately pays the costs of information. If it has occurred to you that you are *already* paying higher prices to cover advertising and promotional costs, then you see the point. Look carefully at the data in Table 6.1. The dollar amounts are impressive (nearly one-half *billion* dollars for Procter & Gamble), but the percentages may be more significant. The percentages can be read as the number of cents out of each dollar spent that go to pay for advertising.* Among the top 100 national advertisers, advertising expenditures run as high as one-fourth of sales [6, p. 30]. Few are that high, but it remains clear that a significant portion of the consumer's dollar goes directly to advertising.

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* The less competition there is, the easier it is for firms to pass higher costs along to consumers. In more competitive markets, there are more firms, so consumers have more choices, and it is harder for a single firm to manipulate price.

This is precisely why information is so important. If advertising efforts were channeled into providing information, there would be a *net gain* to consumers, who would then be receiving something for the costs they are already paying. In that sense, informative advertising would be relatively cheap in that it would be available *at little or no extra cost*. Remember, too, that the potential for advertising as

Table 6.1 Advertising Expenditures: In Dollar Amount and as a Percent of Sales for the 15 Leading National Advertisers: 1976

	Company	Ad Expenditures[a] (in millions)	Ad Expenditures As Percent of Sales
1.	Procter & Gamble Co.	$445.0	8.4
2.	General Motors Corp.	287.0	0.6
3.	General Foods Corp.	275.0	7.6
4.	Sears, Roebuck & Co.	245.0	2.0
5.	Warner-Lambert Co.	199.0	15.3
6.	Bristol-Myers Co.	189.0	9.5
7.	Ford Motor Co.	162.0	0.5
8.	American Home Products Corp.	158.0	8.8
9.	Philip Morris Inc.	149.0	3.5
10.	Mobil Corp.	146.5	0.5
11.	R. J. Reynolds Industries	140.3	2.4
12.	Unilever	135.0	10.7
13.	General Mills Inc.	131.6	4.5
14.	Heublein Inc.	129.1	8.3
15.	Colgate-Palmolive Co.	118.0	3.4

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[a] National advertising, measured media only (includes newspapers, magazines, television, radio and outdoor).

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* These figures actually *understate* the cost of advertising to the consumer because they do not include local advertising (Sears, Roebuck & Co., for example, spends more on local ads than on national) [6, p. 30]. The figures also omit the closely related costs of packaging and promotion.

a mechanism for providing readily available information is difficult to overestimate. The beauty of advertising, as we've noted, is that it reaches everyone; at present, that may be a mixed blessing, but the potential benefits are tremendous. There is no better way for consumers to obtain so much information so effortlessly.

Advertising and Information Content

An Overview of the Media

Thus far we have talked about advertisements as a single group, when in fact there are important variations among them. The most obvious differences are among the media. Television, radio, magazine, and newspaper advertisements come to mind, but they don't cover all the possibilities; there are also specialty or trade publications, billboards, and other outdoor advertisements, flyers, loudspeakers, and other forms that attest to the ingenuity of individual advertisers. If, as Marshall McLuhan says, the medium is the massage, then it is important to understand something about the characteristics of advertising on the various media.

We begin by looking at the distribution of advertising expenditures among the media. A glance at Table 6.2 shows that the top ten advertisers rely heavily upon television (except for cigarette companies, which cannot advertise on television). As a group, these advertisers spent over $1.2 billion on television advertising. Smaller companies spend less on television, but it is the largest firms that represent the bulk of advertising expenditures. Thus, advertising expenditures are highly concentrated in a relatively small number of firms and those firms concentrate on television. The high cost of national television advertising, up to $150,000 for 30 seconds, indicates why television advertising looms so large in the overall expenditure picture [4, p. 74].

Television (particularly national television) is geared to a mass audience; thus, it is less likely that specialized information can be provided. The very nature of television also encourages less informative advertising. Because of its versatility, television can represent a variety of aspects of a product, and there is a natural temptation to use picture and sound to create a mood or an image rather than providing information. In short, television gives the advertiser a means to do a variety of things that don't provide much information.

Radio advertisements present a slightly different situation. These differences follow from the differences in the media, which in turn affect the pattern of radio broadcasting and advertising. This is reflected in the degree to which radio has become specialized; some

Table 6.2 Distribution of Advertising Expenditures by Medium: Top 10 National Advertisers: 1976

			% of Total Dollars							
Ad Rank[a]	Company	Total Expenditures (in millions)	News-paper	Genl. Mags.	Farm Pub.	Spot TV	Network TV	Spot Radio	Net-work Radio	Out-door
1.	Procter & Gamble Co.	362,345.5	1.8	4.5	—	40.2	53.4	0.1	—	—
2.	General Foods Corp.	225,156.6	3.6	9.1	—	29.5	57.3	0.4	0.1	—
3.	General Motors Corp.	203,784.3	19.1	18.2	0.9	13.3	35.3	10.0	0.8	2.4
4.	Bristol-Myers Co.	152,632.7	0.9	16.9	—	11.6	67.3	3.3	—	—
5.	American Home Products	145,189.3	1.5	4.4	0.3	23.1	67.1	2.5	1.0	—
6.	R. J. Reynolds Industries	138,612.6	40.1	30.2	—	4.8	4.2	—	—	20.8
7.	Philip Morris Inc.	134,316.5	33.2	28.9	—	4.7	18.2	1.3	—	13.6
8.	Ford Motor Co.	131,919.7	11.3	16.1	1.7	21.4	37.9	8.5	1.6	1.5
9.	General Mills Inc.	117,934.6	3.3	9.3	—	33.9	49.5	4.0	0.1	—
10.	Unilever	105,586.2	2.7	4.5	—	35.2	57.1	0.5	—	—

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[a] Includes only major media categories for national advertising.

stations broadcast only music—rock, country and western, or classical—while others specialize in news. In metropolitan centers, there are stations that serve particular ethnic groups, while in rural areas, there are farm-oriented stations. Some churches have their own stations, and so do some colleges and universities. With this diversity, it is difficult to generalize about radio advertising. Yet the nature of the medium itself forces certain constraints on radio advertising that limit all stations, regardless of orientation.

It is harder to talk about something than to show a picture of it. If advertisers are going to talk about the product anyway, there is a chance that they will say something informative (although it is possible to talk without saying anything substantive). Most companies have a multimedia advertising package, so that their radio ads complement their television efforts; some companies even run the sound tracks from their television ads.

The printed page is the oldest form of modern communication. It was through the printed media that advertising got its start and took on its present form. Many newspapers and magazines lost advertising revenues to such an extent that some well-known ones have ceased publication. At the same time, others are prospering because they fill a special need of advertisers. There are implications in this situation that directly affect the information that the ads pass along to the consumers.

Newspapers contain a type of advertising that is purely informative—classified ads. These serve the consumer directly by locating items and in effect creating a market. These ads perform the classic function of bringing buyer and seller together. If you were interested in buying a used lawnmower, you might reasonably assume that someone in the area had one for sale; your problem would be finding that someone. It would be very difficult without classified advertising. In its early form, most advertising was of the classified type. Other examples survive, such as the announcements on bulletin boards in neighborhood supermarkets. For the most part, however, advertising has gone beyond these elementary functions and now concerns itself with persuasion and advocacy.

For day-to-day operations in the marketplace, newspapers remain one of the consumer's greatest assets. This is hardly surprising, because newspapers are an important means of local advertising. They afford local advertisers the chance to let consumers know what they have, what specials they are offering, and other information concerning hours and location. In terms of price information, newspaper advertising is probably more useful to consumers than any other type.

Magazine advertising includes a wide variety of approaches. Where color is involved, there is a tendency toward showy, but not necessarily informative, ads. However, like radio and newspapers, magazines have become more specialized, a trend that has hurt mass-circulation magazines. This is significant for consumers, because the general circulation publications contain more general, less informative ads. The specialty magazines, on the other hand, are aimed at a particular audience. It can be assumed that persons reading one of these publications have an interest in the particular topic and perhaps some information about it. During the late 1970s, however, the rising costs of television advertising have renewed advertisers' interest in magazines. At this time, it is impossible to tell how this trend will develop, but to date it has meant more magazine advertising, with the largest increases going to more general, less informative national ads.

A Standard of Judgment

To this point I have discussed advertisements in the rather general terms as being more or less informative. Such judgments obviously require some kind of standard or measure of information content. Various standards have been suggested, but the most common is the content analysis approach used by the Federal Trade Commission (FTC). The FTC is the agency within the federal government that is charged with monitoring advertising; its efforts are gaining more attention, and from time to time you will see that the agency has charged that a certain ad is misleading and must be removed. Such judgments are based on standards that the FTC has developed to classify advertisements into three categories: *informative*, ads that provide significant information; *puffing*, ads that ballyhoo the product without really saying anything about it; and *misleading*, ads that either directly or implicitly misrepresent the product.* These are not necessarily mutually exclusive categories, but they do provide a structure for analyzing information content [13 and 15].

According to the FTC, informative ads provide information on price or relative price, functions of the product, construction specifications, and performance standards. I recall an ad for a chain saw that meets these criteria almost to the letter. The ad shows the saw in use, gives the price ("under $100"), details its features (metal body, self-oiling chain, automatic-recoil start, and so on), and tells something about what the saw will do ("cut logs up to 20 inches in diameter"). If you were in the market for a chain saw, that ad would be helpful; it tells you enough about the saw for you to evaluate it.

Puffing ads, on the other hand, do not provide the consumer with that type of service. They substitute superlatives, endorsements by leading personalities, or claims of uniqueness for hard facts on price and performance. They are fluff (rhymes with puff) and while they may be entertaining, they are not very informative. Soft-drink commercials, which show happy, beautiful people downing gallons of a particular brand, fit into the puffing category. Magazine ads for liquor, which typically feature a close-up of the bottle, are another example. Puffing ads do not mislead, but they do not inform either; as their middle position suggests, they represent a sort of neutral territory.

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* The FTC uses *deceptive* instead of *misleading*.

That may be damning with faint praise, but it is more than can be said for misleading advertisements. Such ads feature unsupported—and often unsupportable—claims and rigged or irrelevant tests, and they portray the product in unnatural situations. These are typical traits of misleading advertisements, but since the range of possibilities is so broad, it is difficult to limit them. Ads may be misleading without resorting to outright lies, though that it not unknown. An advertisement is misleading if it portrays the product as something it is not. There are many examples of misleading advertisements in the history of television, including plastic placed over floors to show a "true wax shine" and shots apparently taken through an automobile window to demonstrate that the glass is distortion-free, when in fact the window had been wound down.

The FTC guidelines sound straightforward enough, but you should appreciate that there are a variety of problems involved in their implementation. First of all, the advertisement may not fit neatly into a single category. An ad may contain features of two or more types. Reliability also deserves mention: One can read, or view, between the lines of advertisements, but it is necessary ultimately either to accept or to reject what the advertisement says. An ad may appear to be quite informative, providing details about the product and demonstrating its effectiveness through different tests. *Appear* is the key word, for it is not always possible to trust what is being said. The track record of advertisers hardly inspires confidence.

Even with standards and a set of criteria for making evaluations, there is bound to be an element of personal judgment in their application. If the price of a product is $99.95, is it misleading to advertise it as "under $100"? Is it misleading to advertise soft drinks with those happy people and their beautiful smiles without mentioning that the drink promotes tooth decay? Most people would probably feel that to call these examples misleading would represent an overly strict application of the standards, but others might not agree.*

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* As a check, students are urged to repeat the evaluations reported in the following section. See suggested projects.

Given that judgments are involved, no absolute standard can be imposed. The real question is whether the FTC's system of content analysis is a workable approach. To test that question, the FTC guidelines were applied to a sample of actual national television advertisements. The results are enlightening in terms of both the approach and the advertisements.

Information in National Television Advertising

For several reasons, television is the logical place to apply the FTC guidelines. As noted above, television accounts for the greatest portion of advertising expenditures, so it is necessary to look to television to see where advertisers spend their money. National ads were selected not only because of their predominant position in advertising budgets (see Table 6.2), but also because they have a greater impact and are not subject to variation from one area to another. Finally, we should note that television advertising is important because the medium is such an integral part of the American lifestyle. Television affects the way we perceive the world and absorb its images. Thus, television not only reflects modern life, it is part of that life.

The results reported here are based on a sample of 321 thirty-second ads videotaped from the three national commercial networks during February 1977. In implementing the FTC guidelines, two intermediate categories were introduced: informative puffing and puffing misleading. This provides a place for ads that are largely puffing but do give some information, or ads that puff away to the point of becoming misleading. The sample was drawn from four designated time segments: weekday afternoon, prime time, news programming, and sports advertising.* Thus it is possible to compare information content for different time segments.

Two raters were trained in the use of the FTC guidelines and each rated the ads independently. The two agreed on their ratings for 84 percent of the ads, and in only 3 percent of the cases did their ratings disagree by more than one category. This suggests that despite variations among individuals, the FTC scale can be applied in a uniform fashion.

The results of the survey are summarized in Table 6.3. A glance at the "total" column shows that half of the ads fell into the puffing category. Puffery, then, is the norm for national television advertising, which means no substantive information is provided. About 10 percent of the ads were judged to be informative. That is not very impressive when you consider that the sample is drawn from about 20 hours of viewing time. So, if you watched 20 hours of television, you would have 17 minutes 30 seconds of informative national ads.

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* Time segments were defined as follows (all times EST): weekday afternoon, 1-3 P.M.; prime time, 8-11 P.M.; sports programming, weekend afternoons; news, weeknight network evening news programming. Note that no children's programming was included in the survey.

It might be heartening to note that there were so few ads judged to be actually misleading. It is possible, however, to argue that there should not be *any* misleading ads. When the misleading and puffing-misleading categories are pooled, nearly 10 percent of the sample contained ads with some misleading elements. The puffing-misleading ads generally earned that designation by exaggeration, gross overstatement, or implications that misrepresented the product. These may be only venial sins, but they still have a negative impact on the viewer consumer.

An interesting pattern emerges when we look at information content by time segment. No striking differences are apparent. Puffing ads predominate in all time segments, although afternoon programming features slightly more puffery and slightly less information than other segments. The most significant feature of the time-segment breakdown is the concentration of misleading ads during the afternoon. Afternoon programming features game shows and soap operas that are commonly oriented toward women; the significance of that relationship will be discussed in the following section. The overall conclusion from the time-segment breakdown is that, in terms of the information content the ads provide, it doesn't matter a great deal when you watch television.

By way of summary, we must say that national television adver-

Table 6.3 Information Content in Designated Time Segments: Numbers of 30-Second Ads

Level of Information Content	Time Segment				
	Daytime Afternoon	Prime	Sports	News	Total
Misleading	7	0	0	1	8
Puffing Misleading	9	7	3	2	21
Puffing	68	30	33	30	161
Informative Puffing	33	15	30	18	96
Informative	12	11	8	4	35
	129	63	74	55	321

Source: "The Relationships Among Information Characteristics and Sex-Role Portrayal in Network Television Advertisements." [24]

tising provides very little information; it is difficult to reach any other conclusion. There are some bright spots—nearly 40 percent of the ads contained some information. Some information, however, isn't a very good showing when you consider the amount of money spent on television advertising and the degree to which it saturates the country. Had local ads been included, the percentage of informative ads would probably have been higher; local ads can provide specific price and product information more easily. However, a higher percentage of informative ads would *not* mean that the percentage of advertising expenditures going to information would be correspondingly higher. A local tire company may advertise a sale and provide the consumer with a great deal of useful information (price, size, and so on). However, that ad will cost only a tiny fraction of the price paid for prime national advertisements. From the consumer's point of view, the local ad is probably a better "buy," but that also means that the bulk of advertising expenditures are going to less informative national ads.

The Problem of Experience Goods

Thus far we have discussed ads in terms of their information content, without reference to the products being advertised. If, however, we are to address the problem of improving information content, we must now broaden our investigation to include consideration of the products in the ads. The basis for that need goes back to our discussion of *search* and *experience* products in the last chapter. Search products, you will remember, are those goods that the consumer can evaluate prior to purchase (the horsepower of an engine or the color of a suit); by contrast, information on experience goods can only be obtained by actually using the product (the taste of a cup of coffee or the effectiveness of a deodorant) [20, p. 315].

You should recognize that experience products are heavily advertised, particularly on television. Foods, toiletries, soft drinks and beer, patent medicines, and many other personal consumption items fall into the experience category.* Furthermore, other products, such as automobiles, combine search qualities with significant numbers of experience qualities. In the sample discussed in the previous section, 223, or nearly 70 percent, of the 321 ads surveyed were judged to be for experience goods [24].

By now you should see the problem. If the only way a consumer can obtain information about a product is to use it, how can any real information about the product be provided in an ad? No ad can tell you how a soft drink will taste, how a hair spray will work, or how you will feel in a particular article of clothing, and yet hundreds of products in these categories are advertised regularly. Since it is the experience that counts, the advertiser must try to convey a feeling for the product through the ad; the experience may be second hand, but if you see all those happy people drinking cola, you might remember the brand name and try the product yourself.

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* The third category discussed in the previous chapter was *credence* goods. These products and services are not heavily advertised at this time. Some products, such as patent medicines, may have credence qualities, but these can be analyzed in experience terms.

The result, of course, is puffery, which helps explain why that category dominates advertising. The advertiser has little choice but to puff, because there is little that can be said about the product.* Nelson, who developed the distinction between search and experience goods, was the first to make this point [19]. His hypotheses were supported by the sample of television ads discussed earlier; the search goods in the sample showed a significantly higher level of information content than did experience goods [24]. Other researchers have found similar results [23].

In some cases, advertisers choose to use puffery when they don't have to. Advertisements for automobiles, for example, can give precise information on price, engine specifications, and construction. Often, however, that opportunity is neglected in favor of showing the car in luxurious settings, where the emphasis in on mood and style and superlatives replace substance ("the most glamorous Baasmobile ever").

Even though some discretion is involved, it remains true that many ads simply cannot be made more informative. It follows that it would be impossible to dictate that advertisements must provide information without forcing significant changes in current advertising patterns. Puffery may be toned down, but it cannot be eliminated because of the very nature of the products being advertised. This presents a serious obstacle to any program designed to improve the overall level of information content in advertising.

An Alternative Approach

The difficulty with experience goods is not the only problem with the content analysis approach of the FTC guidelines. A potentially more serious concern is stated in the question: At what point does a statement become misleading or deceptive? Suppose, for example, that a gasoline ad claims to "Put a tiger in your tank!" That statement is false, and yet hardly anyone would consider the ad misleading. The reason is that everyone knows the statement is false and was not meant to be taken literally.

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* Price is always a search quality, but these products tend to be relatively inexpensive and price differentials may not weigh heavily in the consumer's decision.

That is clear enough in the case of the tiger, but what about other ads in which phrases like "lowest price ever," "best buy yet," or "runs forever" are thrown around? At what point can the consumer reasonably be expected to differentiate between intended puffery and intended fact? The Federal Trade Commission's answer to the problem is the *average man concept*.* An ad is not considered deceptive if the average man can be expected to recognize the intent of the message [1, p. 571].

Given the manner in which the term *average* is abused, that approach doesn't really solve the problem. Are we speaking of the average man in terms of intelligence, education, or experience in the marketplace? If we're talking about the average man on an average day, we must remember that the average man makes mistakes and take that into account. Not surprisingly, there have been a large number of court cases on this point.

The concept makes sense only when some kind of rule of reason is applied and the whole question is viewed in a behavioral context. The question revolves around what individuals are going to believe and how those beliefs affect behavior. Thus, in order to make the content analysis approach work, human behavior has to be taken into account. This fact has prompted some experts in the area to suggest an alternative approach to the deception problem. An ad should be considered deceptive, they argue, only if it affects the consumer's beliefs and she or he then acts on those beliefs in a harmful way [17].

Briefly put, there would be no deception if no one is deceived. An ad might misrepresent a product and thus be termed misleading under the FTC's system, but if no one believes the ad, then there would be no real deception. This *behavioral* definition of deception focuses on the impact of the ad on the consumer's behavior. In order to be put into effect, the behavioral approach would require extensive screening of ads before groups of consumers representing a cross section of the population. The technical aspects of that process would be complex and would quite probably generate disputes.

The behavioral approach doesn't really address the question of improving the overall level of information in ads and is therefore of limited value in that regard. However, it is valuable as a reminder that the ultimate significance of an advertisement lies in its impact on the individual. It is the interpretation of the ad that finally matters, which means some attention should be given to the manner in which individuals treat information from advertising.

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* Presumably, the average man could be a woman.

There is some evidence to show that most consumers approach advertising with a critical eye. Most people assume that advertisers exaggerate; therefore, individuals tend to discount much of what they hear or see in ads. Under such circumstances, it is difficult to deceive a person; the individual's reluctance to accept advertising claims at face value turns out to be the first line of defense against deception. Given that situation, there is a possible danger in efforts to promote truth in advertising. If individuals come to believe that ads must be truthful, they will be more vulnerable to deception. Unless the law is perfectly enforced, advertisers would have more incentive to try and mislead consumers because there would be a greater chance that their efforts would pay off [19]. Things would not have to turn out that way, but they could; the possibility emphasizes the need to take consumer behavior into account when considering advertising. Unless the situation is analyzed fully, well-intentioned efforts could end up having harmful effects.

Current Trends and Developments

Combating Negative Information

The preceding sections dealt with information and deception in advertising in general terms. Before we proceed with the question of the information potential of advertising, we should look at some specific cases and see how these issues are actually working themselves out in the marketplace and the courts. To a considerable extent, that story centers around the Federal Trade Commission. The responsibility for monitoring advertising has been part of the FTC charge since it was founded in 1914; however, it was not until 1938 that the commission was given specific authority to prosecute for misleading advertising when only the consumer interest was involved (see Chapter 8).* It would be wrong, however, to assume that the FTC has acted alone. The following examples show that private consumer groups have been active, and, in some cases, have been responsible for forcing the Federal Trade Commission to act.

One example that shows the impact of private initiative is the advertising campaign run by the Shell Oil Company several years ago. You may recall the ads that billed Shell's *Platformate* as an additive that added significantly to mileage. It showed car after car crashing through a paper barrier, having gone farther than cars using gasoline without Platformate. Unfortunately, the campaign was as flimsy as the paper barrier. True, the cars using gasoline with Platformate did go farther, but as *Consumer Bulletin* was the first to point out, Platformate (or something like it) is found in nearly all gasoline meant for use in automobiles [21]. You could not buy the kind of gasoline Shell was using in the test. Any gasoline purchased from any pump would have Platformate in it and would go as far as Shell's.

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* *Monitor* is the key word here; except in rare cases when litigation is involved, the FTC does not regulate or give prior approval to ads. The agency only reacts to existing ads, often in response to consumer complaints.

Shell maintained that since the ad merely said that cars go farther on Platformate, there was no deception involved. No one bought that argument, however. *Advertising Age*, the trade journal for advertisers, sounded an "Amen" to a letter written by an agency executive that said: "This is the kind of deception that gives all of advertising a black eye and makes the task of the honest practitioner of the craft just that much harder. It's also great fuel for those who promulgate government control of advertising . . ." [3].

Pain relievers represent another area of apparent deception and certain confusion. Aspirin is the main ingredient in such products, and aspirin, it turns out, is aspirin. A 1962 study published in the *Journal of the American Medical Association* indicated that statistically there is no difference in the performance of the five leading brands of pain relievers [12]. That was over fifteen years ago, yet producers still turn out advertisements that claim that their brand is superior, supporting their arguments with supposed *scientific* tests. Students who are familiar with statisical testing techniques know that such claims must be taken with a grain of salt (or perhaps aspirin). There is no evidence that if they were repeated on a larger population the results would be the same.

Nevertheless, the claims continued unabated until finally, in 1973, the FTC entered the case. The FTC filed suit against the major pharmaceutical companies, maintaining they must either provide acceptable scientific evidence to support the claims made for their pain relievers or take the ads off the air. Five years of litigation have not resolved the case and there appears to be no prospect of an impending settlement.

If the Geritol case is any precedent, the question of pain relievers could be in the courts for years to come. Geritol claimed to "strengthen iron-poor, tired blood" or "iron deficiency anemia." No one was quite sure what tired blood was, but experts agreed that iron deficiency anemia is rare in the United States and, in any event, is not usually associated with a lack of iron in the diet [9]. The FTC brought suit, but the case was in the courts for over a decade before the questionable ads were removed.

Protracted litigation is also underway in the Listerine case. For most of this century, Listerine has been advertised as an effective agent against colds. In fact, it is simply a mouthwash, and as Listerine ads now state, it does nothing to kill germs or fight colds. Even so, it took a series of court battles before the claim was removed from Listerine's advertising, and, even now, the notion that the product is something more than a mouthwash may linger on [5]. Because of that possibility, the FTC asked Listerine to do more than simply remove the ads; the company was asked to pay for *corrective advertisements.* Corrective ads, as the name implies, are meant to correct previous misinformation provided to consumers, and are also involved in the Geritol and pain reliever cases (in the latter, the FTC is asking that 25 percent of the companies' future advertising expenditures go to corrective ads).

The FTC had earlier required corrective advertising of a fruit juice company (for false nutritional claims about its drink) and of a diet bread (which claimed to have fewer calories, but in fact was only sliced thinner). In these cases, however, the corrective ads had limited impact because they were so mild. It wasn't really clear to consumers that the companies were admitting any wrongdoing. If corrective advertisements are to be effective in making up for deception, they must be clear and straightforward.

The problems with corrective advertisements are further illustrated in the STP case. As was true with Platformate, it was a consumer organization that originally raised questions about the product (an oil additive). In 1971, *Consumer Reports* indicated that STP was at best unnecessary, and at worst a possible danger to the car's engine [11, p. 422]. The issue was unresolved and STP continued to expand its operations; in so doing, it included performance claims in its advertising, claims that were supported by a series of tests conducted by independent laboratories.

Those tests, however, proved questionable and the FTC brought suit. The case was settled in early 1978 when STP agreed to pay a $700,000 fine and pay for a series of corrective advertisements. The ads were labeled "FTC Notice" and referred to "certain allegedly inaccurate past advertisements." Included in the ad was the statement "Agreement to this settlement does not constitute an admission by STP that the law has been violated" [26, p. 14]. Not only were the ads confusing and seemingly contradictory, but they were run mainly in business publications. The idea was to get the message across to other businesses that the FTC itself meant business; however, the campaign did little to clear up misconceptions that individual consumers might have had about STP.

It is evident that the Federal Trade Commission has become more active in dealing with possible deception in advertising, but the impact of that activity is not yet clear. Advertisers have at least taken notice, but whether future ads will be any different is unknown. If enforcement is sustained, gradual change could take place. If, however, the FTC's activities are seen as isolated events, change seems unlikely.

Children's Advertising

The Federal Trade Commission's activities with respect to advertising have not been limited to the prosecution of individual cases. In an effort to deal with more general concerns, the commission has employed a broader approach in certain problem areas. Children's advertising offers a notable and well-publicized example. The implicit assumption in the *average man* concept is that individuals can make critical judgments about advertising content. In the case of children, that assumption may not be warranted, which marks children's advertising as a topic of special concern.

That concern, however, is a fairly recent development. A decade ago, no special attention was given to children's advertising. Then, in 1968, a group of Boston-area women formed Action for Children's Television (ACT) in an effort to improve the quality of children's programming; advertising was among their first concerns. ACT called for a ban on children's advertising, basing its request on four problem areas:

1. Developmental—young children have not yet developed the cognitive skills to evaluate material presented in advertisements. Thus, children are particularly vulnerable and impressionable [16].
2. Family life—pressure from children to buy advertised products could have a negative effect on the parent-child relationship.
3. Nutritional—concern was expressed with both the dubious nutritional information contained in ads and the poor nutritional content on many heavily advertised snacks and cereals.
4. Content—it was maintained that products (particularly toys) were oversold, leaving a misleading impression of the product's capabilities [18].

The FTC called hearings on these matters, but no further action was taken. However, pressure from ACT brought about a degree of self-regulation by the industry. The number of minutes of commercials per hour of children's programming was cut from 16 to 9½ and performers on children's shows no longer were to promote products. Also, a clear distinction had to be made between the programming and advertising (usually by a fade out or graphic design) [18]. Pressure from consumer groups also induced three vitamin manufacturers to withdraw their advertisements from children's programming.

Through all of this, the FTC's position remained vague; the commission seemed to support the reform efforts, but resisted efforts to force change on the industry [2]. The FTC's period of inactivity stretched into 1977, but then increasing concern with nutrition prompted staff investigations. As a result of the investigations, the following proposals were approved by the commissioners in early 1978. The FTC proposes that:

1. All advertising aimed at children under six be banned.
2. The advertising of candy and highly sweetened cereals be banned from all children's programming.
3. Companies that advertise lightly sweetened cereals be required to spend an equal amount on purely informative nutritional advertising [7].

At this writing, hearings are being held on the FTC proposals. It appears that at least some of the recommendations will be implemented; it is also probable that court challenges await any action the FTC takes. Recent court decisions extend First Amendment rights (freedom of speech) to advertisers, and it appears that litigation will be based on that argument. Whatever happens, the FTC's action (after a decade of indifference) illustrates the power that public opinion can have when it is organized and directed.

The controversy over children's advertising deserves a final comment. The entire argument is built around the idea that advertising, particularly on television, is more than just a way to sell products; it affects the whole pattern of living. That point is particularly relevant to children, but it can be applied more broadly. I've suggested throughout this chapter that advertising is a part of what we commonly call lifestyle; any effort to discuss the issue in narrower terms runs the risk of dangerous oversimplification.

Advertising by Professionals

While the FTC is attempting to limit advertising geared to children, the commission is seeking to promote advertising by professionals—medical doctors, lawyers, pharmacists, and so on. Few professionals of this type have advertised in the past, in part because tradition held that advertising was unprofessional and in part because professional associations banned advertising. The FTC began its efforts to promote advertising by professionals in 1975; a ruling by the Supreme Court in 1977 upheld the right of professionals to advertise and accelerated the rate of change [10, p. 70].

In the last chapter, I indicated that information about professional services falls into the *credence category*, goods or services that cannot be fully evaluated even after they are consumed [20, p. 315]. Professional competence, not advertising, seems to be the key issue. Furthermore, it would be difficult to advertise prices in many cases until diagnosis and treatment were complete. To confound the issue, it is impossible to repress the image of a doctor doing a television commercial in the manner of a used car dealer ("Special, Today Only . . .").

Surely such jokes have circulated around the FTC, but that is not what the commission had in mind. The ban on professional advertising, the commission maintained, denied information to consumers and thus represented a restraint of trade. The logic of the argument is based on the fact that although many professional services are complex and involved, others are routine. A will for a middle-income family, for example, is a rather straightforward document and is relatively inexpensive. However, if there is secrecy about prices, the client-consumer won't know if he or she is actually paying a reasonable price.

The same logic holds for the advertising of prescription drug prices. Once the drug has been prescribed by the doctor, the patient-consumer ought to know where it can be filled most economically [2, p. 1632]. Such drugs must meet federal standards, so there is little risk to the individual. Even in more complicated situations, comparative price information should be helpful. If you find out, for example, that your family doctor is the most expensive in town, it hardly seems unreasonable that he or she be able to justify the expense. The doctor might be worth the price, but if patient-consumers aren't aware of relative prices, they won't be able to inquire.

One of the problems with the pricing of professional services has to do with price discrimination, which means charging different individuals different prices for the same service. In the marketplace, most products are sold at a single price to all consumers, which means that those who would be willing to pay more for the product are getting a bargain; it is easy to see that if each individual is charged the maximum that he or she would be willing to pay, the seller would benefit.*

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* Price discrimination is legal in such cases and may be justified on the grounds that the poor thus receive treatment more cheaply.

Because of the nature of their services, professionals are able to practice price discrimination, but disclosure of fees makes the practice more difficult. Advertising should reduce the range of prices for similar services. Some professionals may resist advertising for that reason.

It is difficult to provide an overall evaluation of the impact of advertising by professionals. Contrary to the expectations of those on both sides of the controversy, it is unlikely that advertising will bring about any great changes. For example, allowing doctors to advertise isn't the answer to rising medical costs. However, in a small way the consumer should benefit. The change isn't momentous, but it is reasonable, and, as in the examples mentioned above, it should help the consumer. There may also be a more subtle, long-range benefit to consumers; more candid information about professional services should promote a more objective approach to the subject, and that should serve the consumer's interest.

Problems and Possibilities

Catching Up to the Present

Our discussion of advertising and information has ranged over a variety of issues; it is hoped that as you covered the material, your thinking about advertising has changed somewhat. The various problems addressed above cannot be dealt with until consumers begin to perceive the possibilities that advertising affords. There are limitations, to be sure, but advertising still has a potential educational and informational value beyond the capabilities of most alternatives. *It is nothing less than a resource*, a badly abused and misused one, but a resource nevertheless.

Putting advertising in that context serves another purpose: It helps us break out of the mental rut we are in when it comes to thinking about the question. Advertising is such a part of our lives that it is difficult to think of it except as it currently exists. Our thinking about advertising is badly out of date. Even when advertising has the potential to reach into every American home instantly, we still think of it in terms of the medicine show or the weekly newspaper. During the last century, advertising was unregulated and often outrageous, but that hardly mattered. If the medicine show advertised a cure for fallen arches, heart attacks, and sore backs, it did so to a small group that could evaluate the product and the advertising. Even if someone was suckered into buying the product, the amounts involved were probably small.

Technological change, however, has altered the situation radically. Faster presses, the introduction of color, and widespread distribution improved the traditional media. Radio and television have spread the reach and potential effectiveness of advertising still further. Frederick Lewis Allen chronicled these changes during the 1920s. The ads of fifty years ago make today's look like the picture of responsibility. For example, Allen tells of the unhappy people who had

> . . . succumbed to pyorrhea, each of them with a white mask mercifully concealing his unhappy mouth. . . . The woman who would undoubtedly do something about B.O. if people only said to her what they really thought. . . . These men and women of the advertising pages, suffering or triumphant, *became part of the folklore of the day.* [8, p. 73, emphasis added]

Those people, or their grandchildren, have become part of American culture and they are treated with a degree of nonchalance that masks their real importance. Consumers continue to treat advertising lightly even though increasing complexities in the market and technological change have reduced consumers' abilities to counter the forces of advertising. You should recognize this argument as an aspect of the more general consumer problem—the consumer's inability to work in a changed environment. Consumers do not seem to have caught on to the fact that the environment has changed, which has permitted the freewheeling and largely unchallenged development of the advertising establishment. The implications of advertising for consumers and its potential usefulness have not really been grasped.

Notice that I have come out in favor of advertising, not against it. My criticism has to do with certain aspects of the way products are advertised, not with advertising itself. Unfortunately, even the mildest criticism of advertising tends to polarize opinions. Some groups seem to feel that there is something sacred about the current content and structure of advertising; they equate the status quo with what they call "our free enterprise system." Whatever that is, it is not a very good description of advertising and the American economy in the 1970s. Advertising expenditures are highly concentrated among a small number of firms. This concentrates a tremendous amount of power in a few hands. It can be argued that, rather than support free enterprise, massive advertising expenditures actually promote monopoly elements by giving an extra advantage to certain firms. Advertising becomes a way of maintaining control of a market and forestalling competition. Thus, a doctrinaire approach only masks the real issues and confuses the question.

Some New Directions

Any change in advertising must begin by educating the public to what advertising *could* be. The success of Action for Children's Television shows that if it is properly organized and directed, public pressure can bring about changes in advertising. Most changes thus far have emphasized limitations, but change can also be cast in positive terms, with the emphasis on realizing advertising's informational and educational potential.

However, it should be clear that it isn't enough to simply say to advertisers: "Thou shalt be informative." As noted, some ads (for experience goods) cannot be really informative. We can reasonably assume that most consumers recognize this fact; the emphasis in such cases should then be placed on preventing distortions and deception. In areas where more informative ads are possible, however, higher levels of information content should be encouraged (and in some cases required).

We can assume that businesses act in their own self-interest, which means that more informative ads will be forthcoming when such ads are in the company's self-interest. That will only happen when consumers begin to demand more information. This is a realistic possibility if consumers are aware that information is available; public service broadcasting might encourage this trend by stressing the kinds of information consumers can expect.

A significant problem with this proposal is validating the information provided in advertisements. Here is where a national information policy comes into the picture. Information provided through advertising would be an integral part of that overall policy. The Environmental Protection Agency has been criticized for its mileage ratings, but at least they have put an end to the gross exaggerations that formerly characterized mileage claims.

EPA ratings must be included in automobile ads, but other public information could be used voluntarily. If tests showed that the Clomp-Clomp lawnmower was the safest, most economical, and most dependable mower on the market, then Clomp-Clomp should be able to use those findings in their ads. The public would know that the company was not just making wild claims, since the information would have been validated. Thus, advertisements would be a way of getting quality information to the public.

Where does that leave companies whose products do not measure up well in such tests? They would not be forced to say that in their ads, but they would not be able to make any claims of performance of quality either. That would provide a powerful incentive to improve their product. Better information flow would therefore bring pressure on producers to offer quality products, which is precisely the way markets are supposed to work. Now producers can hide behind the consumer's lack of information and pass off inferior products.

I have treated advertising at great length simply because it has the potential to provide high-quality, low-cost information to all segments of the population. *Information* needs to be interpreted very broadly in this context. That is, it includes not only information about products per se but also about types of products and services. In short, advertising could perform a genuinely educational function. Insurance advertisements, for example, could include detailed information about types of insurance, strengths of each type, and the best insurance package under different circumstances. Similarly, advertisements for banks or other financial institutions could include sound financial advice. By the ingenuity of advertisers, this information could be put across in an easily understandable fashion. It is difficult to think of a more effective way to get information to a broad cross section of the public. As people were continually exposed to this sort of advertising, they would gradually develop a more sophisticated understanding of these complex issues. Citizens might decide that some percentage of total advertising time should be given over to such educational efforts. In this case, I am not talking about advertising a product, but rather providing information on a class of products or services.* Because ads of this type would be different from product advertising, public trust should be greater.

A program of this sort is based on the idea that advertisers have a responsibility to provide information to consumers. If that information is not contained in ads for particular products, it would be presented in the more general, educational ads.† Some people may feel that advertisers should not be forced to assume a social responsibility, but the proposal only assumes that those who benefit from a system should in turn work toward improving it. Companies have a right to advertise; they also have a responsibility to the public. This is not a very radical idea.

If you think the changes suggested here sound like pipe dreams, remember that changes have already taken place in advertising. It was not too long ago that cigarette advertisements, now banned from television, were making health claims about their products. Similarly, the very idea of corrective advertising would have seemed radical a few years ago. Thus, it is not unrealistic to suppose that advertising over time can be made to convey information. The changes will not take place overnight and the program will not come in a single package. Progress generally comes in small steps. In this case, the ultimate goal makes the journey worthwhile.

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* Advertisers could be required to set aside a percentage of their total advertising budgets to fund such efforts. These costs would be passed along to the consumer, but considering the potential value of such a program, the expense should be well worth it in terms of individual consumer's savings.

† Some hint of this idea is contained in the FTC proposals for children's advertising. Companies that advertise certain types of cereals would be required to pay for ads about nutrition. By extending the idea, advertisers of medicines could fund ads on health, and so on.

ADVERTISING REGULATION BY THE FEDERAL TRADE COMMISSION

by
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INTRODUCTION

The Federal Trade Commission (FTC) has been for many years the principal Federal agency concerned with the regulation of national advertising. At its inception and during its early years, however, this role was negligible. This is so because the Commission's enabling legislation, the Federal Trade Commission Act, was passed by the Congress at the request of President Woodrow Wilson after a long political fight arising out of what was then called the "trust problem." President Wilson envisaged an agency of experts to protect businessmen from unfair acts by competitors. Consumer protection, including protection from unfair and deceptive advertising, was not one of the agency's initial concerns or responsibilities. In the original 1914 Act there was no specific reference to advertising or consumer protection.

It has been through a slow, evolutionary process that the Commission has assumed its present day importance in the field of advertising regulation. This report examines the Federal Trade Commission's activities in this area over the last 65 years, placing special emphasis on new developments during the last decade.

Part I offers an historical perspective on the growth of the advertising industry since the turn of the century. Part II provides a brief discussion of the legislative framework within which the FTC operates. Despite the increase in vigor of the Commission's regulation of advertising that began just about a decade ago, its legal authority that governs this field has changed relatively little over the years.

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The few changes which have taken place have evolved mainly from changes in approaches to enforcement and reinterpretations of existing legal authority. Part III presents a summary of the traditional approaches that the Commission has employed in carrying out its mandate to protect consumers and competitors from false, misleading, deceptive, and unfair advertising. Part IV reviews new developments in advertising regulation during the last decade.

HISTORICAL PERSPECTIVE

Modern advertising is a key element of marketing for business enterprise. It has flourished chiefly in countries and in periods in which private industrial capitalism has been able to achieve rapid and sustained economic growth, support a considerable degree of leisure activity, and provide a high level of consumption for the bulk of the population. Advertising in some form has operated in societies whose markets have been state-controlled, and to a small degree it even thrived in pre-industrial America and in 18th-century England. In neither form, however, did it resemble the type of advertising which has developed during recent decades in the English-speaking nations, and particularly in the United States.

19th Century Developments

The unique importance and complexity of the advertising industry in America is clearly the result of a number of factors which, though not individually restricted to this country, have been combined perhaps more favorably in this country than anywhere else. The industrialization which accompanied and followed the Civil War opened the way for manufacturers to seek ever larger markets within which their expanding production could be accommodated.

It was also during this period that many food processing and consumer-goods manufacturing firms began to advertise their brand names, to package goods under their labels, and generally to induce consumers to look for their products on store shelves. Previously, most consumer goods sold in retail shops were "generic" goods (not differentiated according to manufacturer--often not even identified as to the source). Many products were sold from barrels or jars, with no effort to inform the consumer as to the manufacturer's name.

The last third of the 19th Century was also marked by a continuation and broadening of the transportation revolution, which had already brought to the American economy improved wagon highways, steam navigation on inland waterways, oceans, canals, and the steam railroad. Indeed, as has been said, the late nineteenth century belonged peculiarly to the railroad. The construction of railroads absorbed an enormous portion of American resources and energies. The new railroads, in turn, were of critical importance in stimulating economic expansion. They were the commercial lifelines of an industrializing society.1/

1/ Scheiber, Harry N., Harold G. Vatter and Harold U. Faulkener. American Economic History. New York, Harper and Row, 1976, p. 259.

Simultaneously, mass media expanded on a scale made possible by the cheapness of newsprint, new techniques in periodical publishing, an increasingly mobile population, and the generally powerful political influence of publishers who were able to obtain legislation favorable to the wide circulation of periodicals at low costs to themselves.

As a consequence of these and other developments, estimated expenditures on advertising--mainly in newspapers and magazines, but also on billboards and barns alongside roads, and in streetcars and railroad stations--rose from only about $8 million in 1865, to $200 million in 1880 and to almost $800 million by the end of the century.[1]

Pre-World War I

By the time the Federal Trade Commission was established in 1914, what has been called the "golden age of advertising" was in full swing. The advertising agency N. W. Ayer & Son, which was founded in 1869, had already obtained the first $1,000,000 account and launched the first national campaign--for Uneeda biscuit--using newspapers, magazines and outdoor advertising. Automobile advertising was already big business. By 1914, the car makers were spending more than $4,000,000 a year to advertise. The country was already very much advertising conscious. The Atlantic Monthly and the Yale Review ran articles on the subject of advertising, declaring it to be the most conspicuous feature of American life. Concern was expressed about its effect on the morals, tastes and health of the nation.[1/]

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[1] Scheiber, et al. p. 259.

Indeed, during the period between 1900 and World War I, concern about advertising was very great. The muckrakers, as they came to be known, unleashed a furious attack on phony advertising, starting with patent medicines. Next came exposes of fraudulent financial advertising.

In 1910, Cyrus Curtis, the most successful magazine publisher in America, formulated the Curtis Advertising code, which set forth in specific terms the kind of advertising that would not be carried by Curtis Publications. This covered mainly copy "knocking" competitors, medical copy claiming a cure, and advertisements for alcoholic beverages.[2/]

What has since become the Advertising Federation of America helped launch a campaign in 1911 for truthful and ethical advertising. The association drew up a code and adopted the slogan "Truth in Advertising." Subsequently, Printers' Ink, the industry's leading magazine, joined the campaign and published the Printers' Ink Statute, which was a model state law penalizing false and misleading advertising. Working together, the magazine and the federation lobbied the model statute through 37 State legislatures by the time the FTC Act was enacted.

1/ How It was In Advertising, 1776-1976. Compiled by the editors of Advertising Age. Crain Books, Chicago (1978), 110 p.

2/ Dunn, Samuel watson and Arnold M. Barban. Advertising: It's Role in Modern Marketing. Dreyden Press, Hinsdale, Ill. (1978) p. 32.

The War Years

Following the first World War, during which time much advertising was devoted to the war effort, business enjoyed a marked expansion. A mass market for automobiles came into being, and advertising saw million-dollar budgets become fairly commonplace.[1] With a major assist from the new medium of radio, total advertising expenditures increased from $2,282,000,000 in 1919 to $3,426,000,000 in 1929.[2]

With the Depression, advertising volume slumped some 25%, falling back to about its 1915 level. During the 1930s there was a searching examination of the economic system that had allowed such a debacle as the Depression to happen. One of the frequent targets was advertising. Critics attacked not only its excesses and the products it promoted, but also the very concept of advertising. A parade of best-selling books "exposed" advertising as an unscrupulous exploiter of the consumer.

Some of the opposition to advertising was directed toward legislative initiatives. The proposed Tugwell bill, for example, called for compulsory grade labeling of canned goods, drugs, and cosmetics. A much-modified version of the bill was passed in 1938 as the Food, Drug, and Cosmetics Act. And, it was against this backdrop that the Wheeler-Lea Amendment of 1938 was passed which substantially broadened the power of the Federal Trade Commission to regulate advertising.

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[1] Advertising Age. Nov. 21, 1973, p. 6.

[2] Advertising: It's Role in Modern Marketing. p. 34.

Advertising began to thrive again with the advent of World War II. Unlike World War I, there were few advertisers who abandoned or reduced their advertising efforts for the duration. Despite shortages and scarcity, advertisers deemed it prudent to keep their brand names prominently displayed even when their branded products cound not be purchased.[1] This approach paid off in an unprecedented demand for post-war products and services.

Modern Advertising

The period since the close of World War II has witnessed a number of developments that have been conducive to a dramatic growth in advertising expenditures. The extraordinarily strong and diversified growth of the post-war economy has been, of course, fundamental. This growth brought with it a rapid and sustained increase in discretionary income which paralleled and contributed to a shift toward product differentiation. For a major portion of the population, the post-war period meant a dramatic increase in consumer choice and a significant increase in the money available to spend on those choices.

Probably the most significant direct contributor to the growth of advertising expenditures in this period is television. *Printers' Ink* made the first computation of television advertising expenditures in 1949: $57 million. By 1977, the figure had risen to well over $7 billion.

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[1] Cohen, Dorothy. *Advertising*. John Wiley & Sons, New York, 1972, p. 64.

The advertising industry today is large by any standards and continues to play an important role in the economy. Advertising expenditures totalled estimated $42.9 billion in 1978 or slightly more than 2% of Gross National Product. And, it is estimated that advertising expenditures will increase at an annual rate of 8% over the 1978-83 period, reaching $63 billion by 1983.[1]

LEGISLATIVE FRAMEWORK

The Federal Trade Commission Act

The Federal Trade Commission Act, passed in 1914, provides the basic federal authority for controlling advertising abuse. Specifically, Section 5 of the Act gives the Commission its basic mandate by conferring jurisdiction over "unfair or deceptive acts or practices in commerce." The legislative history of the Act indicates that this was to be an expansive grant of authority:

> The committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid their continuance or whether it would, by a general declaration condemning unfair practices, leave it to the Commission to determine what practices were unfair. It concluded that the latter course would be better...[2]

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[1] U.S. Dept. of Commerce. 1979 U.S. Industrial Outlook, p. 491.

[2] S. Rep. No. 597, 63d Cong., 2d Sess. 13 (1914).

The first case to reach the courts from the new Commission involved the regulation of advertising. The Seventh Circuit upheld the power of the FTC to control deception in advertising, declaring that the Commission had authority to "stop all those trade practices that ... injure competition directly or through deception of purchasers."[1] Thus, promotional advertising quickly became a target in regulation of business practices. In the 1922 case of FTC v. Winsted Hosiery Co.,[2] the Supreme Court added its approval of such regulatory activity by holding that labeling goods containing less than ten percent wool as "woolen" was deceptive and injured commerce by diverting trade from truthful firms.

In three other early cases, however, the Court interpreted the Act so as to limit significantly FTC power over advertising. In 1920 a majority held in FTC v. Gratz[3] that it was proper for the courts to review de novo Commission determinations that a given practice was an "unfair method of competition" in violation of section 5. The Court further held that the range of unfair practices within the Commission's jurisdiction was limited to those unfair practices regarded in 1914 as opposed to good morals or "against public policy because of their dangerous tendency unduly to hinder competition or create monopoly."[4]

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[1] Sears Roebuck & Co. v. FTC, 258 F. 307, 311 (7th Cir. 1919).

[2] 258 U.S. 483.

[3] 253 U.S. 421 (1920).

[4] Id. at 427. See, Developments in the Law--Deceptive Advertising, 80 Harv. L. Rev. 1020, (1967).

This was in large part the consequence of the preoccupation of the framers of the Act with the Commission's role in supplementing antitrust enforcement. Thus, the Commission's intended role, if any, as an agency for protecting consumers against fraud (except in the unlikely circimstance in which fraud might facilitate monopoly) was left wholly undefined.[1] In *FTC* v. *Klesner*[2] nine years later, the requirement was established that the harm to the public interest caused by an unfair practice must be "specific and substantial." The most serious obstacle to FTC policing advertising activity was presented by the Court's 1931 holding in *FTC* v. *Raladam Co.*[3] that the Commission must find that competitors and not merely consumers were injured by the misrepresentation.

Later during the 1930s the Commission was accorded a more receptive treatment by the Court. Recognition of the value of flexibility in determining the bounds of legality under section 5 replaced the static conception of "unfair methods of competition" expressed in *Gratz*.[4] The FTC's potential ability to deal with novel deceptive practices was bolstered further by a narrowing of the scope of review, so that greater deference was given to the Commission's determinations of public interest.[1]

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[1] Posner, Richard A. Regulation of Advertising by the FTC. Washington, American Enterprise Institute for Public Policy Research (1973) p. 11.

[2] 280 U.S. 19 (1929).

[3] 283 U.S. 643.

[4] See, *e.g.*, FTC v. R.F. Keppel & Bro , 291 U.S. 304 (1934)

The Wheeler-Lea Amendments

A number of these conflicts were resolved and the jurisdiction of the FTC was affirmed by the Wheeler-Lea amendments of 1938. The important Section 5 was rewritten to read: "(a)(1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce are hereby declared unlawful."[2] The addition of the phrase "unfair or deceptive acts or practices" made it no longer necessary for the Commission to show that competition was injured. If there was injury to the public, the FTC was empowered to act.

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[1] FTC v. Algoma Lumber Co., 291 U.S. 67 (1934).

[2] In 1975 "in or affecting commerce" was substituted for "in commerce". Public Law 93-637.

The legislative history of the amendments affords strong evidence that Congress believed that the new Section 5 prohibition of "unfair or deceptive acts or practices" (as well as special sections covering the advertisement of food, drugs, medical devices, and cosmetics), provided the Commission ample authority to regulate advertising:

> The definition is broad enough to cover every form of advertising deception over which it would be humanly practicable to exercise government control. It covers every case of imposition on a purchaser for which there could be a practical remedy.[1]

Subsequent court decisions have confirmed the conclusion that the Wheeler-Lea Act firmly established the jurisdiction of the FTC over advertising.[2]

The Wheeler-Lea Act, however, did not provide the FTC with much greater scope than had been granted prior to 1938. Its contributions lie in the confirmation and clarification of the Commission's authority over all types and degrees of deception and its improvement of procedures for enforcement.[3] Previously, the FTC was required to go to the courts for enforcement of an order. If an order was violated, the Commission had to ask the Court of Appeals for an injunction directing the violators to obey. In 1938, the Wheeler-Lea Act gave final effect to orders issued by the Commission if such orders are not appealed by the respondents within 60 days. However, cease and desist orders are still reviewable by the U.S. Court of Appeals and thereafter upon writ of certiorari to the U.S. Supreme Court.

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[1] H.R. Rep. No. 1612, 75th Cong., 1st Sess. 5 (1937).

[2] See, e.g., Fresh Grown Preserve Corp. v. FTC, 125 F.2d 917 (2d Cir. 1942) (false labeling and misbranding); Zenith Radio Corp. v. FTC, 143 F.2d 29 (7th Cir. 1944); Gulf Oil Corp. v. FTC, 150 F.2d 106 (5th Cir. 1945).

[3] Brown, William F. The Federal Trade Commission and False Advertising II, Journal of Marketing (Oct., 1947), p. 201.

TRADITIONAL PRINCIPLES OF ADVERTISING REGULATION

Since the Federal Trade Commission's inception, national advertising has been regulated to a large extent under section 5 of the FTC Act which, as has been discussed, declares "deceptive" or "unfair" acts or practices to be unlawful.

Deception in Advertising

The standard for "deception" has been the "ordinary" or "average" person in the audience addressed by the advertisement, taking into account that many who may be misled are unsophisticated and unwary. Aside from the "ignorant, the unthinking and the credulous,"[1] an advertisement may have a greater or lesser capacity to deceive because of the special susceptibility of the target audience.

In measuring deception (it is only recently that the "unfairness" aspect of section 5 has been frequently viewed or asserted as an independent standard against which claims might be measured), the traditional FTC

1/ Aronberg v. FTC, 132 F.2d 165, 167 (7th Cir. 1942).

practice has been to look at the total impression generated by the advertisement and to reject literal truth as a defense if that impression was false. It is this general principle that supports the rule that if an advertisement is capable of being interpreted in more than one way, and one of those interpretations is false and likely to mislead a substantial portion of the audience, the advertisement is unlawful under section 5.[1]

If an advertisement is deemed to be misleading based upon the evidence, issues of materiality and causality relating to whether consumers were influenced in purchasing decisions by the false claim are largely avoided by the FTC rules that the Commission need show only capacity to deceive rather than actual deception, and capacity to affect purchasing decisions rather than actual effects.[2]

Commission Decides What Is Deceptive

The meaning of an advertisement is a matter entrusted to the discretion of the Federal Trade Commission.[3] Because this seemingly simple fact is a principal reason in the FTC's managing to prevail in the appellate courts in the vast majority of its decisions that have been appealed, it warrants further examination.

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[1] Giant Food, Inc. v. FTC, 322 F.2d 977, 981 (D.C. Cir. 1963), cert. dismissed, 376 U.S. 967 (1974).

[2] Charles of the Ritz Distribs. Co. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944).

[3] Gellhorn, Everett. Proof of Consumer Deception before the Federal Trade Commission. 17 U. Kan. L. Rev. 559, 563-67 (1969).

The most noted case in this regard is *Zenith Radio Corp.* v. *FTC*,[1] where the Commission challenged two sets of claims in a series of advertisements for Zenith radios. First, Zenith asserted in an advertisement that " 'Europe is talking to you every night in English. . . . You can hear all the leaders . . . all the daily news broadcasts.' "[2] In truth, atmospheric conditions prevented satisfactory reception of foreign broadcast every day. It was the conclusion of the Commission that the effect of the claims was to lead people to believe that radio reception difficulties would be completely overcome, particularly because public knowledge of difficulties of radio reception was limited. The second series of claims designated the number of tubes in the radio (e.g. "Eleven-Tuber superheterodyne with Rotor Wavemagnet Aerial"). The Commission defined tubes as devices that perform " 'the primary function of detecting, amplifying, or receiving radio signals.' "[3] Several of the "tubes" Zenith relied on to arrive at a total number of eleven had to do with tuning or converting alternating current into direct current, and therefore did not qualify under the Commission's definition. The Commission held against Zenith after finding that a substantial portion of purchasers believed that a radio is better and more powerful if it has a large number of tubes.

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[1] Zenith Radio Corp. v. FTC, 143 F.2d 29 (7th Cir. 1944).

[2] 143 F.2d at 30.

[3] 143 F.2d at 31.

In affirming the Commission's decisions on both sets of advertising claims, the court of appeals concluded:

> The Commission was not required to sample public opinion to determine what the petitioner was representing to the public. The Commission had a right to look at the advertisements in question, consider the relevant evidence in the record that would aid it in interpreting the advertisements, and then *decide for itself* whether the practices engaged in by the petitioner were unfair or deceptive as charged in the complaint (emphasis added).[1]

Deceptive Comparative Price Advertising

One of the traditional enforcement approaches which best illustrates the shift or change in emphasis which began approximately ten years ago concerns the FTC's 1958 Guides Against Deceptive Pricing.[2] During the 1960s as many as thirty percent of all cease-and-desist orders sought by the Commission related to deceptive (i.e., "fictitious") price claims, such as claims that a product will be sold at "10% off list" or at an "all time low price." With the exception of instances where deceptive price claims have been a part of a broad pattern of fraudulent operations, enforcement of this provision during the last decade has been negligible.

Judging from deceptive pricing cases brought prior to 19[illegible] in which the Commission wrote an opinion, the seller's representation was usually accurate--the sale price was lower than the former price; the compared price was the bona fide manufacturer's list price--and the Commission's complaint was that the seller did not have many sales at the former price, or that, due to widespread discount selling in the local area, the manufacturer's list price was not a common selling price there. Still, the problem with most fictitious price cases is the question of determining what possible consumer or competitive injury occurred. For the most part consumers realize that the price reductions are commonly motivated by the seller's inability to move the item at the former price and that many products are never sold at the manufacturer's list price.[1] The Commission's policy to deemphasize enforcement against alleged deceptive (fictitious) pricing, thereby allowing some exaggeration and ambiguity in price claims, appears consistent with the principle of minimum enforcement where consumers, as opposed to competitors, are unlikely to be seriously injured and where rigid substantiation requirements might suppress a useful form of competition.[2]

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[1] Ibid.

[2] 23 Fed. Reg. 7965 (1958).

Phony Mock-Ups

A second area that received considerable Commission attention during the late 1950s and 1960s concerned the phony use of mock-ups in television advertising. These deceptions occur when the advertiser falsely

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1/ Posner, Richard. Separate statement in report of the ABA Commission To Study the FTC (1969) p. 109.

2/ Pitofsky, Robert. Beyond Nader: Consumer Protection and the Regulation of Advertising. Harvard Law Rev., Vol 90 (Feb. 1977) p. 689.

distorts qualities of its own or competitive products in order to create in the consumer's mind a perception of product qualities that the product does not possess.

The FTC's campaign against mock-ups culminated in the Supreme Court's decision in FTC v. Colgate-Palmolive Co.[1/] In that case, the advertiser sought to demonstrate that "Rapid-Shave" had super-moisturizing properties which permitted the shaving of sandpaper, and thus that it would be effective in shaving the toughest beards. Because sandpaper appears in television transmission as plain colored paper, the cream was applied instead to plexiglass covered with sand, which was then swept clean by a razor. The record showed that sandpaper could not be shaved unless it had been soaked for some eighty minutes, and therefore the demonstration was a clear deception without reference to the mock-up. The Supreme Court went on to find, however, that even if sandpaper could be shaved exactly as demonstrated in the commercial, it was a separate violation to use an undisclosed mock-up, since the advertiser was found to have represented to the public that it was presenting an actual demonstration of its products's qualities. The Court limited its holding so as not to extend to use of scenery as a backdrop, or actors playing roles in "slice of life" commercials, or even the use of mashed potatoes to simulate ice cream, where no product claim is made relating to the simulated demonstration.

[1/] FTC v. Colgate-Palmolive Co., 380 U.S. 374 (1965).

As with the fictitious pricing cases, the major question that the Commission found itself asking about the mock-up cases is what is the extent of injuries that consumers suffer as a result of the deceptions. Judging from the fact that the FTC has not filed a single mock-up complaint in the last eight years, it would appear that the Commission determined that it can best allocate its resources in other areas, and it is probable that national advertisers have taken notice of the legal problems that can result from using these types of deceptive practices.

Violations of section 5 are actionable where the injury is to either competitors of the advertiser or to consumers. When the FTC acted as "a surrogate enforcement arm for competitors",[1] as it frequently did prior to a decade ago, it characteristically became entangled in nit-picking, literalistic disputes over the meaning of words in advertisements. During the 1950s and 1960s, a large number of enforcement actions were the result of complaints received from competitors and appear to have been basically intended to shield sellers against competition from less expensive substitutes.[2]

In the 1969 Report of the American Bar Association To Study The Federal Trade Commission, Richard Posner goes into considerable detail describing hundreds of cases he reviewed involving forced disclosures of what he believes to be irrelevant facts. Posner concludes that insignificant cases "constitute a significant part of the FTC's total output over the years" and that the FTC achieved "precious little consumer protection."[1]

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[1] Posner, Richard. Separate statement in Report of the ABA Commission To Study the FTC (1969) 108-09.

[2] Ibid., p. 109.

NEW APPROACHES TO ADVERTISING REGULATION

Beginning about 1969, the Federal Trade Commission has initiated a large number of proceedings which have challenged major national advertising campaigns as false, misleading, or unfair. During this time there have been unprecedented efforts by the Government to require by rulemaking and adjudication the disclosure of relevant product information. These recent efforts are in sharp contrast to those of earlier years which included many challenges against claims made by small companies selling re-refined oil, hair restorers, combination fruit trees, etc. And while the traditional rules concerning deception, the use of "puffery" in advertising as a defense, and Commission authority to determine the meaning of ads have continued to govern the disposition of most advertising cases in the last decade, the FTC has taken major steps to augment the protection these principles afford.

First, the FTC has developed a separate category of "unfairness" violations, including the failure to undertake prior substantiation of advertisements. Second, the FTC has shifted its efforts away from protecting competitors and toward encouraging competition. It has accomplished this in large part by virtually abandoning its extensive prior efforts to regulate comparative price claims and mock-up demonstrations as discussed in the preceeding section. Finally, the Commission has undertaken some significant innovations in the imposition of remedies.

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[1] Ibid., p. 113.

"UNFAIRNESS" VIOLATIONS

The 1972 decision in FTC v. Sperry & Hutchinson Co.[1] has encouraged the challenging of advertising claims that are "unfair" as opposed to deceptive. Sperry & Hutchinson (S&H) had tried to suppress operations of trading stamp exchanges, small firms in the business of swapping or selling for a fee stamps necessary to fill books for the redemption of merchandise.

By arguing that section 5 applied only to practices which violate the letter or spirit of the antitrust laws or are repugnant to public morals, S & H successfully defended against an FTC suit challenging its practice as unfair. In reversing the decision, the Supreme Court authorized the FTC to enforce section 5 "like a court of equity," taking into account such factors as whether a practice (1) "without necessarily having been previously considered unlawful, offends public policy" as established "by statutes, the common law, or otherwise"; (2) is "immoral, unethical, oppressive, or unscrupulous"; or (3) causes "substantial injury to consumers (or competitors or other businessmen)."[2]

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[1] FTC v. Sperry & Hutchinson Co., 405 U.S.233 (1972).

[2] Ibid. p. 244-45.

Although the Supreme Court's broad grant of authority to the Commission to develop new rules in the area of consumer protection is not specific enough to provide meaningful enforcement guidelines, three types of nondeceptive advertisements emerge that might plausibly be regarded as "unfair": claims published without reasonable prior substantiation; claims which tend to overreach or exploit particularly vulnerable groups; instances in which sellers fail to provide consumers with the necessary information upon which a choice can be made from among competing products.

Substantiation Of Advertising Claims

There is evidence that prior to 1972 advertisers frequently published claims for which they had little prior substantiating data.[1/] That situation changed rapidly, however, as a consequence of the FTC's decision in the *Pfizer* case.[2/]

Although the FTC has required since 1963 that advertisers have substantiation for claims relating to health and safety prior to the dissemination of the advertisements in which the claims are made, it was not until the *Pfizer* decision a decade later that the prior substantiation requirement was extended to other types of claims.

[1/] See Consumer Subcomm. of Senate Comm., 92d Cong., 2d Sess., Staff Report to the Federal Trade Commission on the Ad Substantiation Program (1972).

[2/] Pfizer, Inc., 81 F.T.C. 23 (1972).

The case involved claims by Pfizer that its product "Unburn" contained a special ingredient that anesthetized nerves in sunburned skin. The Commission challenged the claims and unanimously held that it is "unfair" under section 5 to make an affirmative product claim (puffery excepted) without reasonable prior substantiation. Although the law already required that claims must be nondeceptive and truthful when made, the Pfizer decision went further and concluded that even nondeceptive claims not relating to health and safety would be in violation of the law if they were not supported by adequate prior substantiation.

The Pfizer opinion notes that it is impractical to expect individual consumers to run tests on the thousands of products they purchase and that it is more efficient for the seller to run tests once for each product claim. Beyond this, the opinion asserts that consumers are "entitled" to the substantiation information and "should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented."[1/] The opinion, however, is vague in explaining the justification for ad substantiation and fails to consider the costs that might be generated by a substantiation program.

During the first few years after the Pfizer decision, the FTC launched a series of publicly announced, industrywide "ad substantiation rounds" in

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[1/] Pfizer, Inc., 81 F.T.C. 23 (1972) at 62.

which all major advertisers of a particular product, or all advertisers making a certain type of claim, were required to turn over their supporting data to the FTC. The material is examined by the Commission, complaints are issued where the FTC thinks claims are unsupported, and eventually the data are made public.

In the last few years, however, while the Commission has routinely sought substantiation of ad claims from individual companies that it has investigated, it has only infrequently asked for ad substantiation on an industrywide basis. In 1978, for example, only one such request which covered ads that promoted energy-saving appliances and other devices was initiated. One reason, as recently conceded by Chairman Michael Pertschuk, is that industry self-regulatory programs have been effectively carrying much of the burden of keeping national advertising honest.1/

But there is concern at the Commission that advertisers and advertising agencies may be getting complacent about the threat of FTC action and that the Commission may be losing some of the momentum it built up with its highly publicized cases of a few years ago.

One of the major forces behind the heavy use of ad substantiation rounds in the first few years after Pfizer was the influence of Robert Pitofsky who pioneered its use when he was chief of the FTC's Bureau of

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1/ Richard, Gordon L. FTC eyes substantiation revival. Advertising Age, Jan. 29, 1979, p. 79.

Consumer Protection in the early 1970s. Now that he has returned to the FTC as one of its commissioners, it is felt by a number of industry observers that the program will again receive heavy emphasis.

In January 1979, Commissioner Pitofsky, speaking about industrywide ad substantiation rounds, said, "It's a bit of a burden on the staff to analyse the data, but I think its awfully effective at putting reviewers of advertising [inside companies and agencies] in the position of saying, 'we need this substantiation before you can make that claim.'"[1]

Vulnerable Groups

Another category of "unfairness" which the FTC has begun to attack during the last decade concerns the exploitation of vulnerable audiences. This concept could be relied upon to declare certain ads illegal even if the ads were true because they offend some other standard of acceptability;[2] define truth differently when ads are directed to special audiences such as children;[3] or duplicate the concept of deception already in the law.

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[1] Ibid.

[2] At least to the extent that such action would not violate the first amendment. For a discussion on this point see, Robert Pitofsky. Beyond Nader, pp. 671-73.

[3] Ibid., pp. 675-77

So far, the only Commission decision dealing with unfairness since Sperry & Hutchinson has been its case against ITT Continental Baking Co.[1] That case dealt with the charge that the advertising for Wonder Bread was both deceptive and unfair because, in stressing special nutritional features of the product by broadcasting dramatic growth sequences of children, it "exploit[ed] the aspirations of children [and] parental concerns for rapid growth and development...."[2] After holding that the ad was deceptive, the Commission stated that although the same practice could conceivably give rise to both an unfairness and a deception violation, the record in the Wonder Bread case failed to provide evidence of a separate unfairness violation.[3]

Writing in the Harvard Law Review, Robert Pitofsky said, "Reliance on 'unfairness' in the regulation of stylistic excess in advertising is likely to be minimal. First, standards for what constitutes 'exploitation' of 'vulnerable' groups will be exceptionally elusive. Moreover, charges that an ad, though not deceptive, tends to take advantage of a vulnerable group will usually raise controversial questions of excessive government paternalism."[4] Of course, this is exactly the charge that has been made in response to the FTC's controversial proposed trade regulation rule on children's advertising. Pitofsky concludes his discussion on the subject by saying, "Thus, despite the blank-check authorization provided to the Commission in S & H, new limitations on ad "exploitation" grounded on unfairness have not been developed."[1/] One year later, the FTC staff report on children's advertising broke new ground by citing the S & H case and this principle in support of their proposal.[2/]

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[1] 83 F.T.C. 865, modified, 83 F.T.C. 1105 (1973), aff'd, 532 F. 2d 207 (2d Cir. 1976).

[2] Ibid., at 872.

[3] Ibid., at 964.

[4] Pitofsky, Robert. Beyond Nader, p. 684.

Failure to Disclose

The most far-reaching charges the Commission has taken in the area of "unfairness" concern instances in which sellers fail to provide consumers with information necessary to make choices among competing products. While traditional advertising enforcement included efforts to force disclosure of pertinent information, success was relatively limited.

One of the traditional approaches attacked advertisements for deception based on silence. This approach is exemplified by the advertisements of the iron tonic "Geritol". The impression conveyed was that if you suffered from "tired blood", the iron in Geritol would perk you up. What the ads did not tell you (hence, alleged deception through failure to disclose is) that most fatigue ("tired blood") has nothing to do with iron deficiency anemia.

1/ Ibid., at 685.

2/ Federal Trade Commission: Staff Report on Television Advertising to Children [Feb. 1978] 346 p.

The other traditional approach required a finding by the Commission that, in light of express claims in an ad or the nature of the product, failure to disclose pertinent information would be misleading. Thus, in a case in which the FTC failed to make any such findings of deception or of other special circumstances it was reversed with the appellate court noting that the Commission does not have the authority to require advertisers to provide more information.[1/]

In contrast, the Commission has brought numerous cases in recent years based on the principle that the failure [illegible] disclose is "unfair". At least a dozen cases have involved vocational school advertising where there was no disclosure of the percentage of enrollees who failed to complete the course, percentage of graduates who did not obtain employment, and the salaries and employers of graduates who did obtain jobs;[2/] along similar lines, in complaints challenging allegedly fraudulent land sales schemes, separate violations have been charged for not disclosing

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[1/] Alberty v. FTC, 182 F.2d 36 (D.C. Cir.), cert denied, 340 U.S. 818 (1950).

[2/] See, e.g., Lafayette United Corp., [1973-1976 Transfer Binder] Trade Reg. Rep (CCH) 20,499 (FTC 1974); Control Data Corp., [1970-1973 Transfer Binder] Trade Reg. Rep. (CCH) 19,989 (FTC 1972).

specific information about future land development programs and for not informing buyers that the purchase price of lots did not include everything such as sewers, utility hookups, etc.[1/]

In the area of requiring the disclosure of product information, the FTC has also been quite active. In the mid-1970s a number of rules were promulgated that require the disclosure of information concerning such things as the durability of light bulbs,[2/] care labeling of textile wearing apparel,[3/] octane ratings for gasoline,[4/] mileage per gallon for automobiles,[5/] and tar and nicotine content of cigarettes.[6/] In the past few years, the FTC has also proposed disclosure of information with regard

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[1/] See, e.g., AMREP Corp., [1973-1976 Transfer Binder] Trade Reg. Rep. (CCH) # 20,846 (FTC 1975); Horizon Corp., [1973-1976 Transfer Binder] Trade Reg. Rep. (CCH) # 20,845 (FTC 1975). In these cases, the purchase price did not include paved roads, sewer systems, or phone services. Electricity and water were available only at unreasonable prices.

[2/] 16 C.F.R., sec. 409.1 (1976).

[3/] 16 C.F.R., sec. 423.1 (1976).

[4/] 16 C.F.R., sec. 422.1 (1976).

[5/] 16 C.F.R., sec. 259.1, 259.2 (1976).

[6/] The cigarette manufacturers, responding to threatened government action, decided voluntarily in Dec. 1970 to report in their advertisements the goverment test results of tar and nicotine content. See 1971 Antitrust & Trade Reg. Rep. (BNA) No. 482 at A-22 and No. 487 at A-8.

to the potential side effects of over-the-counter antacids,[1] the effectiveness of hearing aids,[2] and the nutritional quality of food.[3]

COMMISSION REMEDIES

Perhaps the most important developments during the last decade in Federal regulation of advertising concern the Federal Trade Commission's efforts to devise a set of effective sanctions for unfair and deceptive claims. The traditional remedy in deceptive advertising cases was the cease and desist order. These defined, generally in fairly broad terms, those categories of claims which had been found to be illegal. Ensuing false advertising of the same type with respect to the same category of products can lead to penalties of $10,000 per day per violation.[4] The only meaningful alternative to these "go and sin no more" orders was to require future advertising to contain affirmative disclosure of particular product information where silence or implications from other express advertising would be likely to lead to continuing misconceptions about the product in the average consumer's mind. This approach is exemplified by the requiring the disclosure of health hazards in connection with smoking cigarettes.

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[1] 41. Fed. Reg. 14,534 (1976).

[2] 40. Fed. Reg. 59,764 (1975).

[3] 39. Fed. Reg. 39,843

[4] This was recently raised by statute from $5,000. See 15 U.S.C., sec. 45 (m) (1) (B) (Supp. IV 1974).

Traditional Remedies Deemed Insufficient By ABA

Many advertisers and advertising agencies, faced with the FTC's insufficient remedies, violated the law with impunity. Given the limited resources of the Commission and the huge amount of advertising it was required to review, many advertisers could determine that their chances of being detected and prosecuted were remote.[1] Furthermore, inasmuch as the average time for investigation and trial of a deceptive advertising case took more than two years, and since most advertising themes are developed to run for a year or less, the challenged advertising campaign usually had disappeared or was about to disappear prior to the time an order could be entered.[2] This lack of effective Government remedies against false advertising was compounded by the virtual unavailability of private remedies and the paucity of counter-advertising by competitors which could expose unsubstantiated or exaggerated advertising claims.[3]

Remedial innovation at the Commission has concentrated on efforts to eliminate this vacuum in law enforcement. In a consent order agreed to in April 1979 involving J. Walter Thompson Co., the world's largest advertising agency, a new remedial approach was offered as an alternative. In a consent order settling Government charges that it prepared deceptive dishwasher advertisements for Sears, the advertising agency was offered an alternative to its the responsibility to substantiate client product claims: advise the client of "all performance claims" it reasonably believes are contained in the ad. The burden of substantiation then would be largely on the client.[1/]

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[1] Report of the ABA Commission to Study the Federal Trade Commission (1969) p. 18.

[2] Ibid. p. 28-31. (Delays of three to five years between complaint and order were found to be common).

[3] Pitofsky, Robert. Beyond Nader. p. 693.

Corrective Advertising

Probably the most significant development in remedial innovation, however, has been the use of corrective advertising. These orders direct advertisers found guilty of disseminating false and misleading claims to inform consumers, usually through the same advertising media that was originally used to disseminate the false claims, of the facts with respect to the claims.

The FTC has asserted several times since 1970 its view that it has the authority to impose corrective advertising, but it was not until 1977, in a proceeding against Warner-Lambert involving advertising of the mouthwash Listerine, that the Commission finally got a Federal court to agree.

The FTC case, based on a 1972 complaint, involved the Commission's contention that for more than a half a century Listerine ads have created the false impression that the product prevents or lessens the severity of colds and sore throats.

1/ J. Walter Thompson settles U.S. charges that it prepared deceptive ads for Sears. Wall Street Journal, Apr. 16, 1979, p. 79.

In April 1978, Warner-Lambert exausted its last avenue of appeal when the Supreme Court refused to review a 2 to 1 court of appeals decision that upheld a 1975 FTC order requiring that $10,000,000 of future Listerine ads carry the message, "Listerine will not help prevent colds or sore throats or lessen their severity." The lower court had, however, deleted from the FTC's correction a "confessional" phrase ("contrary to prior advertising") the Commission considered important.[1]

In the only major corrective order contested in the courts since the Listerine case, an FTC administrative law judge ordered last September that $24,000,000 of future Anacin ads must disclose that "Anacin is not a tension reliever." American Home Products, the maker of Anacin, is one of three companies named in 1973 complaints challenging performance claims for their analgesics products. The $24,000,000 figure is the FTC's estimate of the average annual Anacin ad budget from 1968 to 1973. The one year run imposed for the correction is the same rule of thumb upheld by the courts in the Listerine case.[2] Even though the tension relief claims were dropped in December 1973, the judge said that the evidence showed that consumers continue to believe that tension relief is an important attribute of Anacin.

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[1] High Court Avoids Listerine Ad Case: FTC Penalty Stands. Advertising Age, Apr. 10, 1978, p. 1.

[2] FTC Judge Gives Anacin $24,000,000 headache. Advertising Age, Sept. 18, 1978, p. 1.

Authority to Order Corrective Advertising

The Commission has not brought any major corrective ad cases recently. It has, however, negotiated quasi-corrective settlements with Firestone and STP.

As with all FTC remedial authority, the power to order corrective advertising stems from the broad delegation of discretion under section 5 (b) of the Federal Trade Commission Act, which empowers the Commission to order parties to "cease and desist" unfair or deceptive acts or practices in commerce. Traditionally, the courts have accorded the Commission wide latitude, particularly in antitrust enforcement, to develop remedial approaches.[1/]

Critics of the corrective advertising approach focus on the established rules that all FTC orders must be "prospective" and -- a related point -- that its orders must not be punitive.[2/] They argue that the process of trying to rectify past wrongs places the remedy beyond Commission authority.

Proponents say the fallacy of this argument is the assumption that FTC remedies must be exclusively prospective. This, they maintain, is an interpretation of Commission power that the agency has never accepted and the courts have not imposed. To the contrary, the courts have said that

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[1/] Jacob Siegel Co. v. FTC, 327 U.S. 608, 611 (1946) (judicial review of FTC remedies is limited because the "Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices in this area of trade").

[2/] FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).

the real question is not whether remedy is prospective but whether it is punitive.[1] That FTC orders prevent some significant future illegal effect is the only requirement imposed, and corrective advertising meets that requirement if the effects of prior deceptive advertising campaigns continue to influence consumer purchasing decisions for a substantial period of time after campaigns have been discontinued.[2] Only the use of corrective advertising orders, they say, can dissipate the lingering effects of false advertising.

A principal concern of those who support this new remedial approach is the applicability of the standards put forth by the Commission in the Listerine case to future cases. The record in Warner-Lambert did support each of the findings under the formulation put forth by the Commission, but the Listerine advertising campaign was most unusual. For more than fifty-five years, the manufacturer had claimed in major ad campaigns (broadcast to the date of the suit) that the mouthwash was effective in ameliorating, preventing, and curing colds and sore throats. Additionally, persuasive evidence was presented that purchasers believed the claim at least up to the time of the suit. Finally, Warner-Lambert had conducted, at a cost in excess of $100,000, its own surveys (to test consumer recall of past advertisements) which were introduced into evidence against it. It is reasonable to conclude that comparable proof of "deception - perception - memory" influence would be virtually impossible in most advertising cases.

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[1] Curtis Publishing Co., 78 FTC 1472, 1512-18 (1971).

[2] Pitofsky, Robert. Beyond Nader, p. 695-96.

SUMMARY

Procedurally, there are three fundamental areas in which the Commission can initiate change in order to attempt to better carry out its advertising regulation mandate. The first area involves the legal approaches it employs, i.e., the principles of law upon which its actions are based. The second concerns the priorities it assigns to the various kinds of enforcement activity that are available to it. The third consists of the types of remedies it imposes on those who violate the rules and laws it is charged to uphold.

Legal Approaches

The last ten years have seen the Commission move away from almost total reliance on "deception" as the basis for developing rules and initiating orders towards the challenging of advertising claims that are "unfair". Following the Supreme Court's 1972 decision in *FTC* v. *Sperry & Hutchinson Co.* the Commission has attacked various ad campaigns involving three different types of nondeception. In *Pfizer*, claims for the product "Unburn" were challenged for lack of reasonable prior substantiation. In *ITT Continental Baking Co.*, unfairness with respect to exploitation of vulnerable audiences was charged. Finally, the Commission has promulgated several rules requiring disclosure of product information based on the theory that it is unfair for sellers to fail to provide consumers with information necessary to make choices among competing products.

Enforcement Priorities

In this area, the FTC has substantially deemphasized two areas of traditional enforcement activity. First, cease and desist orders related to "fictitious" price claims have been negligible since 1969 while product quality claims have been more likely to be challenged. Second, the Commission has in effect abandoned enforcement in the area of phony mock-ups in television advertising.

Remedies

In efforts to devise a set of effective sanctions for deceptive or unfair advertising campaigns, the Commission has experimented with correcting advertising orders which direct advertisers found guilty of disseminating false and misleading claims to inform consumers, usually through the same advertising media orginally used, of the facts with respect to challenged claims. Although the Commission has achieved some degree of success, most notably in Warner-Lambert, it will take future corrective ad cases to determine how far the Federal Trade Commission can go.

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Marconian Problems, Gutenbergian Remedies: Evaluating the Multiple-Sensory Experience Ad on the Double-Spaced, Typewritten Page

Albert H. Kramer[*]

> The unconscious depth-messages of ads are never attacked by the literate, because of their incapacity to notice or discuss nonverbal forms of arrangement and meaning. They have not the art to argue with pictures.[1]

The initial observation that must be made about contemporary advertising is that it is enormously effective. Whatever one thinks of America's ability to solve its social problems or repair its automobiles, it is indisputable that America is very good at selling itself goods and services. The advertising community is marvelously skilled at transporting the consumer of an advertisement to a wooded mountain stream and creating the apparently contradictory impression that smoking a cigarette will cool him off.

It is in fact this ability to successfully suggest a sensory experience to the recipient of an ad that makes advertising effective. This phenomenon has only recently come to be understood. Traditionally, both the advertisers and the regulators of advertising have viewed the effectiveness of a message in terms of the linear written word.[2] Now, however, the media have changed. The media

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[*] This article is adapted from remarks of the Director, Bureau of Consumer Protection, Federal Trade Commission, prepared for delivery to the Advertising Law Conference, Shoreham-Americana Hotel, Washington, D.C., October 20, 1977.

These remarks are the views of the author and do not necessarily reflect the views of the staff of the Commission or a majority of the Commissioners.

[1] M. McLuhan, Understanding Media 205 (Signet ed. 1964).

[2] *See* M. McLuhan, Understanding Media 204 (Signet ed. 1964).

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have left the written word behind in a cloud of dust and have created a new environment of multiple-sensory experience of which the written word is a minor part.

Communications theory experts tell us that health warning messages on cigarette advertisements are seldom noticed. The reason they are seldom noticed is that advertisers spend a great deal of money learning to make them go unnoticed. They spend their resources creating a sensory experience (the wooded mountain stream, for example) to which the health warning is extraneous. The advertiser tests different ads to determine the most effective presentation of the central message of the ad, and implicitly, the least effective presentation of the "extraneous" health warning.

We have made great progress in communication theory over the last decade or two. No other industry has exploited social science data as advertising has exploited communication theory. This exploitation is not necessarily evil. Communication theory can be abused, of course, but such techniques, as long as they are not illegal, are perfectly proper components of the American marketplace. It is imperative, however, that regulators of commercial advertising be equally well-versed in communication theory. A very serious problem arises when regulators evaluate the possible falsity, deception, or unfairness of an ad without considering it in the same "sensory experience" context that the ad sought to instill. Despite all the lessons of communication theory—lessons the advertising technicians have learned very well—the regulators and the judges who review their work persist in using a relatively ancient method for evaluation: they first reduce the total sensory experience of the ad—voices, music, graphics, movement, colors—to the written word, via the double-spaced, typewritten memo or brief.

"Those who have spent their lives protesting about 'false and misleading ad copy,' " wrote Marshall McLuhan, "are godsends to advertisers, as teetotalers are to brewers. . . . Since the advent of pictures," he continued, "the job of the ad *copy* is as incidental and latent as the 'meaning' of a poem is to a poem, or the words of a song are to a song. . . . [T]ypography is itself mainly subliminal in effect. . . ."[3]

A recent case illustrates the difficulty of the current approach to advertising regulation.[4] In 1969 and 1970, Beneficial Finance Company ran ads centered around the concept of the "Instant Tax

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[3] *Id*. at 205 (emphasis added).

[4] *See generally* Beneficial Corp. v. FTC, 542 F.2d 611 (3d Cir. 1976), *cert. denied*, 97 S. Ct. 1679 (1977).

Refund." In reality, this "Instant Tax Refund" was merely an invitation to the consumer to apply for a loan from Beneficial at the normal rates and using the normal qualification procedures—information which was not communicated by the total impression conveyed by the radio and television commercials. An administrative law judge of the Federal Trade Commission found that the total sensory experience of those commercials was deceptive and misleading.[5] More important, he found that there was no possible way to modify the phrase "Instant Tax Refund" so that the ad would not be deceptive and misleading.[6] Therefore, he concluded, Beneficial could no longer use the phrase.

The U.S. Court of Appeals for the Third Circuit reversed, 2-1, on that portion of the order and held that the administrative law judge could not require excision of the phrase because of its quasi-trademark value and the First Amendment's general disfavoring of prohibitions on protected speech.[7] A "less restrictive alternative" to deletion would have to be found.[8]

This author does not quarrel with the court's application of First Amendment theory, nor dispute what consumer perceptions of the ad might have been. He does, however, quarrel with the fact that the judges did not evaluate the potential deceptiveness of the ad via the sensory experience it created. Rather, they evaluated the deceptiveness only via the ad's script, reduced to the double-spaced, typewritten page.

A necessary corollary of this view is that as the ad is dulled by reduction to print, the gravity of any perceived falsity, deception, or unfairness is lessened. Implicit in this discussion of the ***Beneficial*** case is the belief that the deception of the "Instant Tax Refund" ad is far more stark when the entire commercial is viewed or heard—when one is exposed to the entire sensory experience of the ad.

Marshall McLuhan has noted that advertisers strive to find and exploit the sensory experiences to which audiences are most responsive.[9] "The need is to make the ad include the audience experience," he wrote.[10] "The product and the public response become a single complex pattern. . . . The steady trend in advertising is to manifest the product as an integral part of large social purposes and processes."[11]

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[5] *Id.* at 614.

[6] *Id.* at 618.

[7] *Id.* at 618-20.

[8] *Id.* at 620.

[9] M. McLuhan, Understanding Media 201 (Signet ed. 1964).

[10] *Id.*

In his widely praised book *The Responsive Chord*,[12] radio-TV ad creator Tony Schwartz put it even more bluntly. Both the FTC and advertising agencies focus on the "truth" of an ad, which may be a very small part of the total sensory experience. The Commission focuses on "truth" because of its statutory responsibilities and the agencies, because, as Schwartz puts it, "they want to *appear* truthful."[13] However, he concludes that both are dealing with "an irrelevant issue. Neither understands the structure of electronic communication. They are dealing with TV and radio as extensions of print media, with the principles of literacy setting the ground rules for truth, honesty, and clarity."[14]

The only important question for the regulators to ask, according to Schwartz, is

> What are the *effects* of electronic media advertising? For an advertiser, the issue of concern should center on how the stimuli in a commercial interact with a viewer's real-life experiences and thus affect his behavior in a purchasing situation. . . .
>
> From the FTC point of view . . . government agencies responsible for safeguarding public well-being should concern themselves with understanding the effects of a commercial, and preventing those effects that are not in the public interest.[15]

Judge Bazelon has also noted the importance of evaluating the *effect* of advertising as follows:

> In an age of omnipresent radio, there scarcely breathes a citizen who does not know some part of a leading cigarette jingle by heart. Similarly, an ordinary habitual television watcher can *avoid* these commercials only by frequently leaving the room, changing the channel, or doing some other such

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[11] *Id.*

[12] T. SCHWARTZ, THE RESPONSIVE CHORD (1973).

[13] *Id.* at 20.

[14] *Id.* An analogous situation can be found in the fact that the Federal Communications Commission has recognized that visual techniques, as well as words, may be subject to regulation in its handling of "subliminal perception" advertising. Subliminal perception techniques generally involve a superimposed statement, such as "Buy It," flashed on the screen for such a short duration that the viewer may not consciously see the message. In a Public Notice on January 24, 1974, the Commission noted that "[w]hether effective or not, such broadcasts clearly are intended to be deceptive" and are against the public interest. 44 F.C.C.2d 1016, 1017, 29 R.R.2d 395 (1974).

[15] SCHWARTZ, *supra* note 17, at 20-22.

> affirmative act. *It is difficult to calculate the subliminal impact of this pervasive propaganda*, which may be heard even if not listened to, but it may reasonably be thought greater than the impact of the written word.[16]

In contexts other than advertising, regulators seem to recognize their obligation to tailor their method of review to the sensory experience of the medium.[17] Films generally have been considered as distinct from other forms of expression for First Amendment purposes because of the inherent charactertistics of the medium.[18] Moreover, in obscenity cases, the U.S. Supreme Court has recognized that it is the dominant theme of the material taken as a "whole" that must be considered[19] and has recognized a duty to review allegedly obscene material in its chambers before making a determination on obscenity.[20] In the famous "sound truck" case, Mr. Justice Frankfurter made very explicit the notion that different forms of media deserve different analysis:

> The various forms of modern so-called "mass communications" raise issues that were not implied in the means of communication known or contemplated by Franklin and Jefferson and Madison. Movies have created problems not presented by the circulation of books, pamphlets, or newspapers . . . . Broadcasting in turn has produced its brood of complicated problems hardly to be solved by an easy formula about the preferred position of free speech.[21]

Thus, in other contexts, the Supreme Court has often acknowledged a principle that seems to impeach the fairly widespread practice among regulators of accepting a sensory experience via the double-spaced, typewritten pages of a brief. The Court's approach is instructive for regulators who must evaluate allegedly false, misleading, or deceptive ads and shape an appropriate remedy.

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[16] Banzhaf v. FCC, 405 F.2d 1082, 1100-01 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969) (emphasis added).

[17] Despite this Article's emphasis on sensory advertising in electronic media, it may be possible that its analysis would be equally valid if applied to the print media. None of these remarks is intended to eliminate that possibility.

[18] Burstyn, Inc. v. Wilson, 343 U.S. 495, 501-02 (1952). (While the Court acknowledges film as a significant medium for the communication of ideas, any "capacity for evil" it may possess is relevant in determining the permissible scope of community control, but not allowing "unbridled censorship.")

[19] Miller v. California, 413 U.S. 15, 24 (1973); Roth v. United States, 354 U.S. 476, 489 (1957).

[20] *See* Jenkins v. Georgia, 418 U.S. 153, 161 (1974).

[21] Kovacs v. Cooper, 336 U.S. 77, 96 (1949) (Frankfurter, J., concurring) (citations omitted) (prohibition against the use of any sound truck or computer located upon public streets or places emitting "loud and raucous" noises).

The problem this Article has addressed is part of a broader one. The media have become so powerful that they have shaped many societal institutions, including the First Amendment itself. The media have molded "expression" into an image which promotes their power—because the media need the First Amendment. The time has come to recognize that the First Amendment protects expression itself, not just the *representation* of expression.[22] To the extent there is any mandate to regulate false, deceptive, or unfair advertising expression, regulators must be sure to consider the expression itself and not just a representation of the expression.

If advertising regulation is to be effective against advertising that makes its point through use of advanced communications techniques, it is imperative that both regulators and the courts take account of the media revolution, of the advanced market research that enables advertisers to know just what effect a certain message will create, and of the handicap under which they, as regulators, labor if they continue to prescribe ancient, pedestrian remedies for sophisticated but false, deceptive, or misleading sensory experiences that advertisers have created.

Only then will the regulators be dealing in the same currency as the advertisers they regulate.

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[22] Cohen v. California, 403 U.S. 15, 26 (1971) (the "Fuck the Draft" case) (A state may not, consistently with the First and Fourteenth Amendments, make the public display of a four-letter word on one's jacket a criminal offense. The Court noted that much linguistic expression "conveys not only ideas capable of relatively precise, detached explication, but otherwise inexpressible emotions as well.").

No Matter What the Sheepskin Looks Like, It's Still the Same Old Wolf: A Reply to Mr. Kramer

Wesley J. Liebeler*

Having been a misfit even at the "Old" Federal Trade Commission because of my insistence on viewing problems in a market context, it comes as no surprise that I have difficulty understanding what the leaders of the "New" Commission are all about. While I think I understand the words, I must admit that somehow the total sensory experience of Mr. Kramer's message[1] tends to pass me by. After some reflection though, a familiar strain comes through: it's the government that knows what's *really* good for you.

At first Mr. Kramer's argument seems simply to be that the true meaning of some advertisements that include voices and pictures cannot be determined solely by reference to a transcript of what the voices said. That, of course, is a perfectly obvious proposition. A pictorial sequence could show the same person being carried into the baths at Lourdes as a cripple and coming out like a track star. The voices could say nothing or, more appropriately perhaps, they could provide information on train schedules in southwestern France. In a more modern context we might substitute Geritol for Lourdes, but the result would be the same. In neither case would the obvious claim of restorative power be reflected in a written transcript of the advertisement.

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[1] Kramer, *Marconian Problems, Gutenbergian Remedies: Evaluating the Multiple-Sensory Experience Ad on the Double-Spaced, Typewritten Page*, 30 Fed. Comm. L.J. 35 (1978).

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Few of us would attempt to evaluate advertisements like these by "protesting about 'false and misleading ad copy.' "[2] The pictures, sounds and so on are just as much a part of the advertisement as the meaning of the words involved. Indeed, in the examples I have given, the non-verbal part of the ads carries the real message.

The usual approach would be to take the words and music (or pictures) together, to place ourselves in the "environment of multiple-sensory experience," if you must, and specify the claim which the two (or more) different forms of communication state. Sometimes, as in the Lourdes and Geritol examples, the pictures and other "multiple-sensory" part of the advertisement will expand the claim that is made by the words alone. At other times the non-verbal portion of the ad will constrict the apparent claim being made by the words alone. An example of this may be found in the recent Commission proceeding against "Dry Ban," where the pictures were used to limit and restrict the meaning of a verbal claim that the deodorant in question was "dry."[3]

In either case, however, whether the non-verbal portion of the ad constricts the claim of its verbal segment or expands that claim, the total ad is examined *so as to state the specific product claim which the ad is making*. That product claim can, of course, be expressed in words, whether it was actually made in words or in some other way. I would, indeed, have thought that it was necessary to express that claim in words if its truth or falsity were to be made a legal issue. That necessity, of course, arises out of even a modest regard for advising respondents of the nature of the claims being made against them.

Be that as it may, it would be hard to quarrel with Mr. Kramer if his only point was that we should look at all parts of an advertisement in our attempt to state the precise claim which the ad makes, the truth or falsity of which claim is to be assayed in our proceeding. As I have said, that is a perfectly obvious proposition; the Commission already does it.[4]

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[2] *Id.* at 36, quoting M. McLuhan, Understanding Media 205 (Signet ed. 1964).

[3] Matter of Bristol-Meyers Company, 85 F.T.C. 688 (1975), at 743, 750.

[4] In the Dry Ban case the administrative law judge not only had the filmed commercials themselves, he also had marketing surveys which had been conducted by the respondent which showed how viewers perceived the ad, i.e., what message they received from it. But there was more. Commissioner Hanford reported:

> Judge Hanscom's finding that these representations were false is based primarily on an experiment which was performed by complaint counsel

But Mr. Kramer is saying much more than that. He is not concerned that we look to the entire ad to guide our statement of its claim. He positively rejects the idea that we should attempt to draw from the entire ad any statement whatever of its perceived claim. He objects that the old-fashioned regulators "persist in using a relatively ancient method for evaluation: they first reduce the total sensory experience of the ad—voices, music, graphics, movement, colors—to the written word, via the double-spaced, typewritten memo or brief."[5]

Of course, if we are not to "reduce the total sensory experience of the ad . . . to the written word," of an ad claim, we need not concern ourselves with the truth of such a claim or even with the question of whether an intelligible claim has been made at all. Apparently, the only thing that counts is the effect of the advertisement:

> The only important question for the regulators to ask, according to Schwartz, is "[w]hat are the *effects* of electronic media advertising? For an advertiser, the issue of concern should center on how much the stimuli in a commercial interact with a viewer's real-life experiences and thus affect his behavior in a purchasing situation. . . .
>
> From the FTC point of view . . . government agencies responsible for safeguarding public well-being should concern themselves with understanding the effects of a commercial, ***and preventing those effects that are not in the public interest***."[6]

What are these effects? Which ones are "not in the public interest"? One possibility is that Mr. Kramer wants to measure effect in terms of the "sophisticated but false, deceptive, or misleading sensory experiences that advertisers have created."[7] This, of course, would make the Federal Trade Commission the guardian of our fantasies, or at least of those fantasies that are somehow prompted by commercial speech.

A more likely possibility is that Mr. Kramer would view an ad's effect in terms of its ability to affect consumer "behavior in a

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> in his presence and replicated on videotape. In this experiment, Dry Ban was sprayed on glass and on a human forearm and was found to be "wet, runny, liquid and watery" and to leave an "obvious residue." Respondents, however, object to a finding of wetness based on this demonstrative evidence because of the fact that in the experiment the product was sprayed downward, contrary to ordinary usage.

Id. at 742-43.

[5] Kramer, *supra* note 1, at 36.

[6] *Id.* at 38 (emphasis added).

[7] *Id.* at 40.

purchasing situation." I suppose that we may put aside all ads that do not have the ability to induce a positive response from consumers; they will presumably not be around very long in any event. How do we determine which of the remaining ads, those that do have an ability positively to affect consumer behavior in a purchasing situation, produce effects that "are not in the public interest"?

I cannot avoid the conclusion that the ads that are not in the "public interest" must be those ads that effectively induce us to buy products that it is not in the "public interest" for us to buy. What is in the "public interest" for us to buy is, I venture to suppose, a matter for Mr. Kramer and his colleagues at the "New" Federal Trade Commission to decide.

The basic problem with Mr. Kramer's approach is that it turns the purpose of advertising regulation at the Commission on its head. The Commission is supposed to police advertising so that consumers can more efficiently learn about real options open to them in the market. Armed with this information they (we) then make choices that seem best to them (us). The fact that some, or even many of us will choose to eat "junk" food, smoke cigarettes, buy "gas guzzlers" or do something else that fails to meet with the approval of those who run the Federal Trade Commission is absolutely irrelevant. When the Commission acts to reduce the flow of true (non-deceptive) messages that would lead us to purchase such "unworthy" goods it substitutes its judgment for ours. It is in that way and to that extent that Mr. Kramer's approach reverses the real purposes of the Commission's program to police false advertising.

The difference between Mr. Kramer's proposal and the Commission's more orthodox approach is not merely a difference of degree or a shifting of emphasis. These two approaches are in fundamental and irreconcilable conflict with each other. Kramer would concern himself with the effects or end-state of the market process, of which advertising is only a part. If those effects or results do not measure up to some exogenous standard, one that is not derivable from the choices that consumers actually make, the process itself (or at least the advertising portion of it) stands condemned.

A market approach to the policing of advertising—the approach on which the Commission's original charter in this area is presumably based—is legitimately concerned only with the *process* by which consumers receive the information on which they base their purchasing decisions. This approach does not concern itself with the nature of the choices which consumers make. The public interest in the production and sale of particular goods and services is something that is determined by the purchasing decisions of consumers themselves.

While I could develop the differences between these two different approaches to the policing of advertising in an extended theoretical discussion, let me close by contrasting these different approaches in the context of some recent remarks by the Commission's chairman. The Commission must confront, Mr. Pertschuk is reported as having said:

> . . . the realities of a marketing system run amok, a system in which neither incentives nor rewards bear any rational relationship to society's needs, a system which most rewards the sellers of the least healthful foods, a system which in its cumulative impact has produced a bounty of malnutrition . . . .
>
> We are similarly witness to a bizarre market system which rewards the delivery of health care services—whether or not they are needed—but provides little or no rewards for the preventer of disease—for example, the physician who would devote his life to teaching consumers about the relationship between nutrition and health.
>
> By removing competitive restraints on the providers of health care, we free them to communicate with consumers on the importance of diet and sound nutrition as well as on the costs of medical services. We are in effect promoting a competitive system in which medical practitioners teach consumers about the relationship between nutrition and health; consumers demand better quality food; and an increased supply of nutritious food products results.[8]

Mr. Pertschuk objects to the food marketing system because of the *result* which he claims it produces—"a bounty of malnutrition." Aside from the fact that his characterization of that system resembles more the carping of a chronic malcontent than a realistic description of the food marketing system, it is additionally deficient in that it does not explain what aspects of the food marketing process produce this unfortunate alleged result. The system is wrong because it produces results that Mr. Pertschuk does not like—we consumers are simply not eating enough health foods. A market approach to this "problem," if such it is, might ask what it is that prevents existing firms in the food industry, or new entrants into it, from advertising the virtues of eating nutritious foods, presumably in connection with their efforts to sell the same. What prevents these purveyors of wholesomeness from hiring doctors and other professionals to spread the word that will both meet "society's needs" for an increased demand and supply of "better quality food" and at the same time increase their own profits? Nothing as far as I know.

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[8] *See* FTC: WATCH, January 27, 1978, at 9.

The Commission's approach to the health care industry, the other matter addressed by Mr. Pertschuk, was quite different. Here, and in the related fields of prescription drugs and eyeglasses, the Commission identified specific factors that directly impeded the efficient operation of the market *process* itself. With prescription drugs and eyeglasses, a skein of state laws and regulations prevented price advertising at the retail level. The Commission moved directly against those restrictions on the operation of the market for price information. With medical services, there are restrictions, both legal and "professional," on advertising of prices and other factors important to consumers in their selection of medical suppliers along with a virtually endless system of other guild-like restrictions on the effective operation of the market for medical services. The Commission is also moving against these restrictions.

The justification for the medical services, prescription drug and eyeglass programs is vastly different from what Mr. Pertschuk seems to have in mind as regards nutritious foods. The former programs are based on the proposition that various legal and institutional factors in those markets are interfering with the ability of consumers to get information that would enable them to make better choices in the market *in terms of their own standards*. Reduced to its fundamentals, Mr. Pertschuk's problem in the nutrition field seems to be that people are eating too many Twinkies and drinking too much Coke, when they *should be* on a diet of bean sprouts and papaya nectar. As every *sensible* person *ought* to know, that is bad for our health.

Could be. But I doubt that the harm is equal to that which would be produced by the remedy that Messrs. Pertschuk and Kramer seem to have in mind.

By Denise M. Trauth and John L. Huffman

New U.S. Supreme Court Philosophy on Advertising Faces Opposition

Court ruling in two cases that commercial advertising has First Amendment protection is in conflict with actions of agencies on behalf of consumers.

► The U.S. Supreme Court is currently in the process of establishing a revolutionary doctrine that assures the right of consumers to receive certain information and the right of proprietors of the information to disseminate it. In establishing this doctrine, the Court is pulling together dicta from both "access" and "commercial speech" cases. At the same time, there appears to be a movement under way in some segments of society that in many ways is in direct conflict with the Court's developing doctrine. The resolution of this conflict may have profound implications for the future of advertising.

The Supreme Court's Doctrine: The first major case in the enunciation of this new doctrine, *Kleindiest v. Mandel,*[1] decided in 1972, sprang from the denied request of a Belgian Marxist theoretician for temporary admission to the United States to participate in several academic conferences. Mandel and the group of American university professors who wished to hear the Belgian speak appealed the denial and contended that the First Amendment was violated by the statute used to refuse Mandel's entry.

Although the high Court denied Mandel's right to enter the U.S., it took this opportunity to re-inforce the contention of the appellees—a point the Court itself had made in several earlier cases:[2] the right of citizens to receive information is indeed contained within the ambit of the First Amendment.

Kleindiest vs. Mandel, in dealing with the right to receive political information, was a philosophical vestige of the '60s. All subsequent major cases in the development of the new doctrine emanated not from movements to receive political information, but from ones to receive commercial messages.

In *Bigelow v. Virginia,*[3] the right of a newspaper to carry certain kinds of advertising was at issue. Although abortion during the first trimester of pregnancy was held lawful by the U.S. Supreme Court in 1973, the state of Virginia continued to enforce a statute which prohibited encouraging or prompting abortion through advertising. Bigelow, managing editor of a weekly newspaper in Charlottesville, carried an advertisement for a New York abortion service and was convicted of violating the Virginia law.

In reversing Bigelow's conviction, the Supreme Court deviated from an earlier line of cases which had placed commercial speech beyond the scope of the First Amendment, and established the doctrine that speech is not stripped of its constitutional protection merely

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[1] 408 U.S. 753(1972)

[2] "It is now well established that the Constitution protects the right to receive information and ideas. 'This freedom (of speech and the press) . . necessarily protects the right to receive. . .' *Martin v. City of Struthers* 319 U.S. 141 (1943), p. 143. . ."*Stanley v. Georgia* 394 U.S. 557 (1969), p. 564.

[3] 421 U.S. 809 (1975).

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because it appears in the form of a paid political advertisement.

Bigelow is important not only because it establishes protection for commercial messages but also because it justifies that protection on the basis of the public's need for the information contained therein. In so doing, the Court erases the theretofore important legal distinction between speech falling into the political or public interest (*i.e.*, speech necessary for the maintenance of democracy) and therefore protected category, and speech falling into the commercial (*i.e.*, speech not related to self-government) and therefore non-protected category.[4] Thus the Court is admitting that at times political and commercial speech may be one and the same.

The rationale for affording Constitutional protection to commercial speech was expanded in a third major case, *Virginia State Board of Pharmacy v. Virginia Consumer Council.*[5]

Pharmacists had long been part of an elite group of professionals including medical doctors, lawyers and certified public accountants who refused to allow their membership to advertise their services under pain of expulsion from the professional society. This prohibition on advertising by pharmacists was challenged in the present case by a group of prescriptive drug users who felt that their constitutional rights were violated by the ban.

In supporting the consumers' contention, the Supreme Court stressed the fact that there are two addressees of First Amendment protection: the disseminator and the receiver of information.

The Court reaffirmed this when it answered the assertion of the dissent that no right to receive the information that another wants to disseminate exists—at least not when the person objecting could obtain the information in another way, in this case by calling several pharmacies and asking about prices. The Court said:

> We are aware of no general principle that freedom of speech may be abridged when the speaker's listeners could come by his message by some other means, such as seeking him out and asking him what it is. Nor have we recognized any such limitation on the independent right of the listener to receive the information sought to be communicated.[6]

Although the dissent in this case seems to be focused on the distribution of information, the motivation behind this focus is an attitude toward commercial speech. In *Valentine v. Chrestensen*[7] the high Court had ruled that speech which is wholly commercial is outside the ambit of the First Amendment. Although in the 34 years since that ruling the Court had faced the question of constitutional protection for commercial messages several times and had even begun in recent years to afford some such protection to advertisements, as in *Bigelow*, it had never explicitly brought commercial speech under the mantle of the First Amendment, partly because it had always been able to attach the constitutional shelter to some "editorial" element in the advertising copy. In *Bigelow*, this requirement was satisfied by the Court's belief that some Virginians would be interested in the advertisement for abortion due to a curiosity regarding the laws of other states.

In the *Board of Pharmacy* case, because no argument was made favoring protection for the advertisement based on viewing some element in it as editorial matter, the Court felt compelled to face the issue squarely.

Quoting prior cases that dealt with the issue of constitutional protection for commercial speech, the Court noted,

> Our question is whether speech which does 'no more than propose a commercial transaction,'...is so removed from any 'exposition of ideas'...and from 'truth, science, morality and arts in general, in its diffusion of liberal sentiments on the administration

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[4] For a discussion of the role of the First Amendment in guaranteeing our capacity for self-government see Alexander Mieklejohn, *Free Speech and Its Relation to Self Government*, (New York: Harper, 1948)

[5] 425 U.S. 748(1976).

[6] *Ibid.*, p. 757 note 15.

[7] 316 U.S. 52(1942)

> of Government,"...that it lacks all protection. Our answer is that it does not.[8]

Although this case is usually remembered because it brought commercial advertising under First Amendment protection and because it broke the barrier that had kept members of professional societies from advertising, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* went a long way toward securing the rights of consumers interested in receiving commercial messages. The Court did this by establishing the fact that many Americans' interest in commercial information may be keener than their interest in political issues. And this interest may be based not only on personal preference but also on economic realities:

> Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs; yet they are the least able to learn, by shopping from pharmacist to pharmacist where their scarce dollars are best spent. When drug prices vary as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of pain or the enjoyment of basic necessities.[9]

The Court went on to upgrade the status of commercial information by explaining that the "public interest element," ordinarily considered a precondition to affording constitutional protection to any form of speech, is inherent in advertising of the sort at issue:

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what produce, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable...And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decision making in a democracy, we could not say that the free flow of information does not serve that goal.[10]

In this eloquent defense of advertising's value in a capitalistic democracy, the Court seems to be retiring the dichotomy it begot 34 years before in *Chrestensen* between speech in the public interest category—speech which is necessary for the maintenance of democracy—and speech in the commercial category—speech which is not related to self-government.

Lest there be any question that this was indeed the intent of the Court, it took the opportunity to apply the reasoning of *Virginia State Board of Pharmacy* to another set of facts when it adjudicated a case dealing with advertising by attorneys, *Bates v. State Bar of Arizona.*[11]

Bates grew out of a complaint filed by the Arizona State Bar Association against two attorneys who violated a State Supreme Court disciplinary rule by advertising their legal services in a newspaper. The Arizona State Supreme Court upheld the bar association conclusion.

In reversing the decision of the high Court of Arizona, the U.S. Supreme Court began with an affirmation of its judgment in *Virginia State Board of Pharmacy* that speech should not be denied constitutional protection "merely because it proposed a mundane commercial transaction."[12] But the Court was not content to simply re-assert protection for commercial speech. It went on to justify this protection by elaborating on the theme of consumer needs argued so effectively in the Virginia case:

> The listener's interest is substantial: the consumer's concern for the free flow of commercial speech often may be far keener than

[8] 425 U.S. 748(1976), p. 762.

[9] *Ibid.*, p. 763

[10] *Ibid.*, p. 765

[11] 433 U.S. 350(1977)

[12] *Ibid.*, p. 364

> his concern for urgent political dialogue. Moreover, significant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. . . And commercial speech serves to inform the public of the availability, nature and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system. [Citations omitted.][13]

This acknowledgement on the part of the Court that when advertising fulfills the informational needs of consumers it serves an "indispensable" role in the smooth functioning of our free enterprise system reflects the Court's consciousness of an important fact: in the second half of the 1970s, the attention of many Americans is not focused on the philosophical/political concerns of the 1960s but rather on the conditions of economic survival.

Advertising Restrictions: Ironically, it is at this time when the relative position of advertising as a form of free speech has been elevated and its significance noted by the Supreme Court that we see the growth of counter movements in several sectors—movements, in some instances triggered by these very cases, aimed at restricting or inhibiting the advertising of certain products and services.

Although these two developments are serving opposite purposes, both spring from the same source: they are based on an increased awareness of the importance and influence of advertising in contemporary society.

Most groups or individuals attempting to curb a type of advertising appear to focus their attention against radio and television commercials, apparently because of a belief in the assumed power of the electronic media.[14] The movement that most typifies this conviction is one aimed at restraining advertising directed toward children.

A number of disparate groups are presently lobbying to control the kinds and number of commercials directed toward children. Legislatures in California and New York are considering laws that would regulate children's television advertising. The public interest group Action for Children's Television has recently received a $40,000 grant from the Rockefeller Family Fund to aid its attempt to limit the number and kinds of advertisements broadcast during Saturday morning television. And the National Association of Broadcasters has asked the former chairman of the Federal Communications Commission Richard Wiley to update the children's television guidelines for the NAB Television Code.

But the organization most likely to have an impact on the exposure of children to television commercials is the Federal Trade Commission under the leadership of consumer-protection-oriented Michael Pertschuk. The FTC chairman's drive to regulate advertising aimed at children is based on the desire to debunk the assumption that the standards applied to television commercials directed at children need be no different from those governing print ads directed at adults:

> Children are not sophisticated consumers. One advertising man described the role of ads directed toward kids as "guided missiles." That's a very vigorous image. It raises the question of whether children of 2, or 3, or 4 are properly the subjects of well-developed techniques of promotion and manipulation through the most powerful medium the world has ever known.[15]

The Federal Trade Commissioners are presently studying an FTC staff report on television advertising to children which focuses on commercials for products high in sugar which are aimed at young children. This report suggests that the Commission institute a rulemaking procedure to determine whether it should a) ban all television advertising aimed at children under eight years of age, b) ban television advertising of products that pose a serious dental health risk to children under 12 years of age, and c) require that advertisers of products high in sugar content balance these commercials with nutritional and/or health disclosures paid for by the advertisers themselves.[16]

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[13] *Ibid.*

[14] It is interesting to note that this societal concern about the relative power of the electronic media vis-a-vis the print media was articulated as a legal concern as long ago as 1943 in *National Broadcasting Co. v. United States* 319 U.S. 190 (1943).

[15] John Weisman, "We Will Be Embarking on a Long Fight with Advertisers," *TV Guide*, Vol. 25 (November 12, 1977), p. 10.

The staff report argues that such rules would not violate the First Amendment rights articulated in *Bigelow*, *Virginia State Board of Pharmacy* and *Bates*, since advertising aimed at children can be distinguished from other types of commercial speech precisely because of the primary role advertising plays in our society: according to the FTC staff, the Supreme Court brought commercial speech under the First Amendment because the Court viewed material presented in the advertisements in question as essential to rational market behavior.

The staff report argues that since "children lack the maturity to make difficult consumer decisions based on an assessment of factual information,"[17] coupled with the fact that (p)resent televised advertising for sugared products to children is also 'false,' 'misleading,' and 'deceptive,'"[18] banning television commercials aimed at children would not violate the rational-market-behavior theory of protection for advertising propounded in *Bates* and its forerunners.

This argument's logic cannot be employed in an attempt to restrain commercial messages aimed at adults. Two recent efforts to limit advertising of certain products and services provide examples of various arguments used to restrict the flow of commercial information.

The first deals with an issue analogous to the one presently before the FCC: a movement to restrict radio and television advertisements for products containing saccharin without banning the products themselves. In March 1977, the Pure Food and Drug Administration decided that since saccharin was determined to be carcinogenic in laboratory tests conducted by the Canadian government, products containing it should be removed from markets in this country beginning in July 1977.

Because of questions regarding the validity of the Canadian tests plus the popularity of sweet but sugarless foods in America, an outcry ensued from both the public and the food industry. In an attempt to reach a compromise, bills were introduced into both Houses of Congress which mandated more study of the issue during an 18-month moratorium on the product ban. An amendment to the Senate bill called for restricted saccharin product advertising on radio and television during the moratorium. The rationale for the amendment, sponsored by Sen. Edward Kennedy, was that consumers should be told in advertising that products containing saccharin may increase the risk of cancer.

Although both Houses defeated measures to restrict saccharin product advertising, it should be noted that the Senate Amendment which was to require the inclusion of a health warning in all broadcast ads for artificially sweetened products was defeated only after intense and costly lobbying on the part of broadcasters[19] by the not-so-wide margin of 52-42. A second Senate vote to reinstate the amendment and end all saccharin product advertising on radio and television was defeated, 55-39.[20]

A second attempt to limit the flow of commercial messages to adults is apparent in the responses of the individual states to the aforementioned *Bates* case.

Because the facts of *Bates* posed the issue of advertising in newspapers, the Court not only did not deal with the question of extending constitutional protection to radio and television commercials promoting legal services, but also pointed out that "the special problems of advertising on the electronic broadcast media will warrant special consideration."[21] The justices left it to state supreme courts to stipulate procedures that attorneys who wish to advertise in the print media should follow in grappling with the "special problems" of radio and television advertising. It should be noted that the Court did not distinguish between print and broadcast advertising in either *Bigelow* or *Virginia State Board of Pharmacy*.

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[16] "Federal Trade Commission Staff Report on TV Advertising to Children." *Advertising Age*, Vol 49 (February 27, 1978), pp 73-74.

[17] *Ibid*

[18] *Ibid*

[19] "Saccharin ad ban suffers another set back by Senate," *Broadcasting*, Vol 46 (September 19, 1977), p 42

[20] "Saccharin Legislation—Sweet Victory for Broadcasters," *NAB Highlights*, Vol 3 (September 26, 1977), p 1

At its annual convention in August 1977, the American Bar Association discussed the issue and recommended that the states allow lawyers to advertise via print media and radio, but that left the question of television commercials in limbo. The concern of the ABA, and that of many individual lawyers, appears to be that television advertising will diminish the dignity and professionalism of the law because of the entertainment context of virtually any television commercial coupled with what some ABA members consider the tastelessness of many commercials.

Various state medical associations have begun to emulate the bar associations in moving to restrict certain kinds of advertising in the wake of *Bates*. The California Medical Association, for instance, has approved a stringent set of guidelines controlling print advertising and ruling out broadcast advertising entirely.[22]

Conclusion

It would seem that a number of important elements in society—administrative lawmaking bodies, various professional associations, and concerned citizen groups—are determined that advertising must be placed under a number of restrictions if society is to be best served. It would also seem that the Supreme Court is moving in a direction that would culminate in the removal of most restrictions on commercial advertising. At some point these differing philosophies will come into more direct confrontation, and the resolution of that confrontation will have major implications for both advertising and the media it supports.

[21] 433 U.S. 350(1977) p. 384

[22] "California Ad Rules Established for Doctors," *Advertising Age*, Vol. 49 (April 3, 1978), p. 59

The Defense of a False Advertising Case

By ROBERT A. SKITOL

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I MUST SAY that my assigned topic conveys a false and misleading impression. The topic is "The Defense of a False Advertising Case," which of course implies that the Federal Trade Commission (FTC) is still in the business of bringing cases against false advertising. While the word "false" still appears in many FTC advertising complaints, a better description of the Commission's current approach is that it is in the business of bringing cases against perceived implications which the advertiser insists were not conveyed by its advertising but which the Commission nevertheless alleges to have been conveyed without a "reasonable basis," whatever that means.

In short, these days many of the respondents in FTC advertising complaints have become respondents not because they have made false, or unsubstantiated, claims on purpose but because they did not anticipate how the FTC would later interpret, or perhaps *mis*-interpret, their advertising. While the advertiser may have gone to great expense to develop substantiation for every representation thought to be included in the ad copy, the advertiser developed nothing to substantiate the truth of implications the Commission later alleged.

I would not venture any blanket statement as to the reasonableness of the Commission's interpretations of advertising. It is safe to say that sometimes the Commission's interpretation is quite far-fetched, and the advertiser could not have anticipated any such reading. Other times, however, the representation found by the Commission probably is conveyed to many consumers, and the adver-

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tiser's failure to foresee the problem is a product of its own tunnel vision; some advertisers read ads literally and fail to consider possible implications conveyed by a viewing of the ad as a whole. In the interests of diplomacy, I will not express an opinion as to which of these circumstances best explains the majority of FTC complaints.

Substantiation

Of course, even if an advertiser has the foresight and ingenuity to anticipate every possible reading of its ad that may later occur to the Commission and its staff, and even if it goes to great lengths to assemble substantiation for every such reading before the ad is disseminated, it could still end up on the receiving end of a Commission complaint. As to any one of several implications, the Commission may consider the assembled substantiation insufficient to constitute a "reasonable basis."

The Commission's definition of "reasonable basis" is like Mr. Justice Stewart's remark about obscenity: "I can't define it, but I can recognize it when I see it." In every decision to date, the Commission has explained the reasonable basis doctrine in vague generalities, insisting that its meaning is to be determined "on a case-by-case basis." This entirely *ad hoc* approach—what is reasonable in your case may be held unreasonable in mine—offers little guidance to those intent on avoiding trouble with the Commission.

I'm sure no one disagrees with the principle that advertising claims should not be made up out of thin air; an advertiser should have a factual basis for a product claim before it is disseminated. This proposition is about as controversial as apple pie and motherhood. The problem is, however, that according to the Commission, you need something more than any factual basis; you need what at least three of the five Commissioners will consider "reasonable" under all of the circumstances surrounding your claim.

Thus, the Commission's advertising cases now tend to focus on two issues: whether the challenged ads conveyed the representations alleged in the complaint and, if so, whether the advertiser possessed and relied upon a reasonable basis for them. I would like to offer a few thoughts on how to deal with these issues, before as well as after the Commission comes knocking at your door. I would then like to comment on several other issues likely to arise in an advertising case.

The Issue of What the Ad Represents

On the issue of whether the ads conveyed the representations alleged in the complaint, the Commission staff will rely heavily on what they regard as a black-letter rule of FTC law, namely that the Commission can properly determine the meaning of an ad from its own reading of the ad itself, without any evidence of how the ad was actually perceived by consumers. But to hedge their bets, the staff will often introduce evidence to support their view of what the ad represents. In some cases,[1] the staff has relied on market surveys obtained from the advertiser's files. The surveys that have been used for this purpose include those generally used by advertisers to test consumer recall of a particular advertisement, or to gauge consumer attitudes toward the advertised product after some exposure to the advertising. While such surveys may not have been designed to determine how consumers interpret the advertising, the staff's expert witnesses will find that they support the staff's own view as to what the ads represented.

In defending against this kind of evidence, the respondent can certainly call its own experts to refute the staff's experts and attempt to explain away whatever surveys have been introduced. Beyond that, however, the respondent may develop its own survey evidence as a part of its defense, commissioning a survey geared to the specific representations alleged in the Commission's complaint. Any such effort should, however, proceed with caution. It is not beyond the realm of possibility that a specially designed survey for this purpose would end up supporting the complaint allegations. More often than not, the results will be mixed; given almost any random but sizeable group of consumers, there will be at least some who read the ad at issue the way the Commission alleges. If the survey shows that 90 percent of consumers read the ad the way respondent contends but the other 10 percent read it the way the complaint alleges, you will have produced a nice piece of evidence in support of the complaint.

This set of circumstances suggests some steps that might be considered *before* the FTC ever gets around to considering a complaint. First, whenever an advertiser reviews the results of market surveys concerning its ads, thought should be given to how those results might be construed as suggesting an implication that was not previously intended to be conveyed. If any such implication is found, and the truth of the implication cannot be substantiated, the advertising copy should promptly be revised to remove that problem.

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[1] *E.g., ITT Continental Baking Co.*, 83 F. T. C. 865 (1973), *aff'd*, 532 F. 2d 207 (CA-2 1976); *Bristol-Myers Co.*, 85 F. T. C. 688 (1975) (complaint dismissed).

Second, the advertiser might consider conducting, at an early stage, a survey to assess how consumers interpret a new advertisement. If an objective survey of this sort is conducted before an ad is disseminated, and the results reveal no implications that are not fully substantiated, the advertiser will have a strong piece of evidence in its defense in the event of an FTC challenge.

The "Reasonable Basis" Issue

On the issue of whether the advertiser possessed and relied upon a "reasonable basis" for the alleged representation, the staff's position will be that whatever respondent did to support its claim it was not enough. If respondent relied on expert opinions, the staff will say that there should have been a "scientific test"; if there was such a test, they will say that that test was not good enough, or that its results supported at best, a narrower claim than the one actually made. The stage is then set for a battle of experts, those called by the staff testifying that the substantiation is worthless and those called by respondent defending the documentation as impregnable and conclusive.

There are other possibilities for defending on this issue, approaches not fully tested or explored in any case to date. I would argue that since the reasonable basis doctrine requires an assessment of the reasonableness of the steps the advertiser took to substantiate a claim before it was disseminated, it invites consideration of the steps other firms in the same industry take or have taken to substantiate the same or similar claims. What are the available testing methods, the usual standards applied, the prevailing practices throughout that industry? What is the "state of the art," the kind of substantiation generally recognized by responsible firms in the industry as a sound basis for such claims? The respondent should have a full opportunity to develop such evidence through pretrial discovery. I would caution, however, that there are dangers in this approach, and it could backfire in some cases. It also has a few worrisome implications in terms of the Commission's future development of the reasonable basis doctrine.

Another possibility is post-complaint testing designed to show that the representation at issue was and is truthful. Of course, such a showing may not in itself excuse the advertiser's failure to have had a reasonable basis before the claim was disseminated. Post-complaint testing is, nevertheless, relevant to the issue of whether the documentation respondent possessed and relied on before the ad was disseminated was in fact "reasonable" from an objective standpoint. It may also be helpful in asserting and supporting a First Amendment defense—of which more later.

The "Reliance" Issue

One element of the reasonable basis doctrine, as it has been articulated to date, is that the advertiser must not only possess but also rely on adequate substantiation before a claim is made. In some recent cases, the staff has zeroed in on this requirement. The scenario is as follows. Shortly after an ad is disseminated, the advertiser receives an investigative demand, commonly called a "6(b) order", for all documentation in the advertiser's possession for certain representations allegedly conveyed by the advertising. The advertiser responds by denying that his ads conveyed the representations listed in the order. Not anticipating the staff's next move, the advertiser chooses to stand by that denial and, therefore, does not submit any substantiation for the representations listed in the demand.

Shortly thereafter, the Commission issues a complaint alleging that the ad conveyed the representations listed in the 6(b) order, and alleging that they were made without a reasonable basis. The advertiser answers by denying that any such representations were made and, in the alternative, asserting that if they were made, they were supported by a reasonable basis. The staff then attempts to foreclose the advertiser from introducing evidence of any reasonable basis for the representations at issue. In effect, they argue that the advertiser is bound by its response to the 6(b) order; the failure to submit any documentation in responding to that order establishes conclusively that the advertiser had not relied on a reasonable basis before the ad was disseminated.

Exclusionary Rule

After several mishaps with this strategy, the staff asked the Commission to amend the rules of evidence to prevent an advertiser from coming in with new substantiating materials after a complaint is issued. After three years of thinking the matter over, the Commission has complied with the staff's wishes; a new rule entitled "Exclusion of Evidence in Adjudications" (also called the "Exclusionary

Rule") will go into effect on October 26, 1977.[2] It provides, in sum, that if an advertiser is required through compulsory process to submit substantiation for an express or "implied" claim in an ad, the advertiser will not thereafter be allowed, in a reasonable basis proceeding, to offer into evidence anything that was required to be but was not timely submitted in response to the compulsory process. There is one exception built into the rule; materials not submitted in response to compulsory process will not be excluded if the advertiser demonstrates in a hearing, and the Administrative Law Judge finds, that "by the exercise of due diligence the material could not have been timely submitted in response to the compulsory process, and that the Commission was notified of the existence of the material immediately upon its discovery."[3]

The Commission expects this rule to simplify advertising cases; I have some doubt as to whether it will have any such effect. Indeed it may complicate and lengthen the proceedings by introducing issues as to what was "required" to be submitted previously and whether new materials could not have been submitted at an earlier time "by the exercise of due diligence." The validity of this rule will also be challenged on a host of constitutional and statutory grounds. In the meantime, however, every advertiser should keep the rule in mind when faced with an order to submit ad substantiation. Such orders generally require the submission of "all" substantiation for designated claims. The word "all" must now be read literally, and the response must include everything which the company might later need for its defense at trial if a complaint is issued. Thus, such an order could require submission of roomfuls of documents, plus a great deal of corporate information and accumulated knowledge not generally kept in documentary form.

Fourth Amendment Standards

In short, this new Exclusionary Rule may have the unintended and undesired effect of requiring the Commission staff to wade through mountains of material not genuinely helpful to any concern for truth in advertising. It may also have the effect of rendering the Commission's standard investigative demand for ad substantiation unreasonable on its face under Fourth Amendment standards. The

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[2] Commission minutes of June 15, 1977, at 2, reflecting action taken at open Commission meeting of same date (42 *F. R.* 56489).

[3] *Id.*

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Commission will be forced to defend these demands in judicial enforcement proceedings, where they just might be held too broad and thus unenforceable.

My topic, however, is not the defense of a judicial proceeding to enforce a 6(b) order; that may become a very good topic for next year's conference. Returning to the defense of an advertising case, the best defense against the staff's new focus on the "reliance" element of the reasonable basis doctrine is making sure that what you do rely on to support a claim is reflected on paper before the claim is made. If, for example, the basis includes expert opinions, those opinions should be set down in writing. If the claim is susceptible to validation by a test of some sort, it would be advisable to conduct such a test and record the results before the claim is made. Then make sure that whoever in the company is ultimately responsible for approving advertising actually sees the assembled documentation—that he does *rely on* materials that may later become the advertiser's most important evidence in defending against an FTC complaint.

Constitutional Issues

Aside from the issues of what the ad represents and whether the advertiser possessed and relied upon a "reasonable basis," there are some basic constitutional issues which should not be overlooked. The reasonable basis doctrine has yet to be subjected to a full-scale review in the courts. To the extent that this doctrine imposes a new barrier—a vague, ill-defined "prior restraint"—to the dissemination of truthful advertising, it raises serious First Amendment questions. To the extent that it shifts the burden of proof in a Section 5 proceeding, it also raises due process questions.

The First Amendment issues are of particular interest, in light of the recent Supreme Court decisions confirming that truthful commercial advertising is indeed entitled to First Amendment protection.[4] Even if the reasonable basis doctrine, in and of itself, is not held to violate First Amendment rights, the kind of remedy the Commission is seeking in some of its pending advertising cases may be vulnerable to a First Amendment challenge. In some of these cases, the Commission seeks an order prohibiting any representation within a broad category unless it is supported by a "scientific test." Thus, even if a representation included in the specified category is truthful, and fully substantiated by materials other than a "scientific test," it would be banned by the Commission's order. This would appear to impede the free flow of truthful and informative commercial information which, as the Supreme Court has held, the First Amendment protects.

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[4] *Bates v. State Bar of Arizona*, 45 U. S. L. W. 4895 (U. S. June 27, 1977); *Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc.*, 425 U. S. 748 (1976).

In other cases, the Commission seeks an order of "corrective advertising," requiring future ads to include confessions about prior ads. The fact that the *Listerine* corrective ad order has now been upheld by a court of appeals[5] hardly ends the constitutional issues raised by that remedy. The *Listerine* order may still be reviewed by the Supreme Court, and other pending cases in which the Commission seeks corrective advertising present variations that may make such relief even more vulnerable to constitutional attack.

Magnuson-Moss

One part of the 1975 Magnuson-Moss amendments to the FTC Act may prove to have major implications for advertising cases. I am referring to the section which provides that "[i]f the Commission determines in a proceeding [under Section 5] that any act or practice is unfair or deceptive, and issues a final cease and desist order with respect to such act or practice," the Commission may commence an action to obtain civil penalties against any company "which engages in such act or practice" with "actual knowledge that such act or practice is unfair or deceptive and is unlawful" under Section 5. In plain English, if the Commission finds, in a proceeding against company A, that a certain kind of advertising is unfair or deceptive and, thereafter, company B disseminates the same kind of advertising, the Commission need not waste time bringing an administrative proceeding against company B; it can sue company B in district court seeking imposition of heavy civil penalties.

This section raises several intriguing constitutional issues, which are not likely to be fully resolved by the courts for several years. In the meantime, the Commission will proceed with confidence that this new authority is constitutional; thus, its decision in a proceeding against one advertiser will have the effect of an order which is binding on every other company with "actual knowledge" of it. The "actual knowledge" requirement will prove unimportant; the Commission will simply mail its decision to all companies believed likely to engage in the practice it has found unfair or deceptive. In effect, every final adjudicative decision becomes the equivalent of an industry-wide rule.

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[5] *Warner-Lambert Co. v. FTC*, 1977-2 TRADE CASES ¶61,563 (CA DofC. Aug. 2, 1977) (see also opinion denying petition for rehearing, Sept. 14, 1977).

Given the implications of this new authority, it is now quite clear that the named respondent in an advertising case is not the only company with a direct and substantial interest in the outcome. Particularly in a case involving a novel theory, where the Commission is challenging a fairly common practice as unfair or deceptive, numerous advertisers, or trade associations on their behalf, may have a strong claim to a right of intervention and active participation in the litigation.

Suppose that the Commission sues company A for engaging in a certain industry-wide practice. Company A may not have the resources, or the inclination, to litigate the case. On the other hand. company A may not wish to be subjected to an order which is not equally binding on all of its competitors. Negotiating a settlement in the standard manner will not result in an order binding on others; it is generally acknowledged that only Commission findings in a litigated case will trigger the new Magnuson-Moss provision. Thus, company A and complaint counsel work out a deal, a new way of "settling" an advertising case. Both sides agree on the form of the order which should be entered in the event that the Commission finds a violation. The parties then stage a perfunctory trial, putting in evidence in the form of affidavits—just enough to allow the Administrative Law Judge and then the Commission to make findings of fact and conclusions of law. The judge and the Commission make the prearranged findings and conclusions, and then issue the order that the parties had negotiated and agreed on beforehand. The Commission's decision and order are then mailed to every other firm in company A's industry. The Commission advises all of those firms that they are now bound by A's order, even though they did not participate and may not have even known about the proceeding.

What I have just described is not a far-fetched hypothetical case; it is, in substance, what is actually happening in the Commission's pending *Block Drug* proceeding. It may or may not result in Commission findings legally binding on Block Drug's competitors; any attempt to apply such findings to Block's competitors would seem vulnerable on a great many grounds. Nevertheless, Block Drug's competitors face an uncertain, and uncomfortable, future. If they had sought and been able to intervene and actively participate in this proceeding when the case began, they might have avoided this situation.

Settlement Procedures

Not all respondents in advertising cases will be inclined to follow the *Block Drug* approach; some may prefer the more conventional way of negotiating a settlement. Unfortunately, the Commission has just adopted a rule that makes the more conventional settlement procedure a bit more cumbersome. This rule provides that when a provisionally accepted consent agreement and order are published for the sixty-day period of public comment, they will be accompanied by "material submitted to the Commission reasonably related to the merits of the order that is not exempt from disclosure under the Freedom of Information Act, and any other information which [the Commission] deems helpful in assisting interested persons to understand the terms of the order."[6] As the Commission noted at the time the rule was issued, this language means "that most documents submitted by the respondent" in the course of settlement negotiations "would be made available to assist in public comment."[7] That this rule may have a chilling effect on consent negotiations was clearly recognized at the time it was adopted; indeed the Commission stated that in view of "the risk to the negotiating process," it would "review the effect of this rule change after one year."[8]

In the meantime, the message to all respondents is clear: avoid putting anything in writing, unless you are willing to have it made public if and when a settlement is reached and published for comment. Negotiating an order of any complexity without putting concepts and proposals in writing can be rather difficult, but that seems to be the prevailing practice since the new rule was promulgated this past August.

Conclusion

In sum, these days it is hard to devise an effective advertisement immune from some risk of an FTC "reasonable basis" complaint; it is hard to mount an effective defense when such a complaint is issued; and it is hard to negotiate a settlement. On the other hand, it is far from clear that the new Commission leadership intends to issue complaints in any substantial number. The Commission's resources are now so committed to, on the one hand, massive Magnuson-Moss rulemaking proceedings and, on the other, an ever-increasing multitude of studies, evaluation projects, task forces and seminars that it seems unlikely to have many lawyers available for preparing and litigating cases. The new Commission leadership has been strong on rhetoric, adroit at public relations, and quick to announce new initiatives. Whether it will deliver on its promises remains to be seen.

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[6] 42 *F. R.* 39659 (Aug. 5, 1977).

[7] *Id.*

[8] *Id.*

Of course, even without any new initiatives, the new directions this Commission inherited from its immediate predecessors (the Kirkpatrick, Engman and Collier Commissions) are more than enough to keep advertisers on 24-hour alert. Given the Commission's avowed determination to protect consumers against even remotely deceptive implications in advertising; given the vagaries and uncertainties of the reasonable basis doctrine; and given the implications of the Exclusionary Rule and the threat that under the Magnuson-Moss provisions a proceeding against one advertiser may produce an order binding on a whole industry, more than ever before the advertising game is strictly hazardous duty. **[The End]**

DOES THE 1ST AMENDMENT PROTECT FRANKENBERRY?

Selling to Children: Fair Play in TV Commercials

by *JOHN CULKIN*

A recent ad in *Broadcasting* magazine invited sponsors to buy time on a new television station in Boston.

Kid Power Is Coming to Boston

If you're selling, Charlie's Mom is buying. But you've got to sell Charlie first.

His allowance is only 50¢ a week but his buying power is an American phenomenon. He's not only tight with his Mom, but he has a way with his Dad, his Grandma and Aunt Harriet, too.

When Charlie sees something he likes, he usually gets it.

Charlie and Charlene, the kids in the two- to twelve-year-old range, attract a half billion dollars of TV advertising annually. Most of the commercials directed at them are for food and toys. These TV spots generate billions of dollars in sales. The question now before the Federal Trade Commission is whether or not the advertisers are acting fairly in their dealings with children. Rules proposed in February by the Commission staff include:

1. The prohibition of all television advertising directed at children under eight, because such children are "too young to understand" the purpose of the ad.

2. A ban on advertising highly sugared products to children under twelve since such products pose "serious dental health risks."

3. A requirement that advertisers fund health and nutrition messages to be broadcast during children's viewing times.

The Commission has asked for public comment on these proposed rules, but the hearings it plans to hold in Washington and San Francisco are unlikely to produce any surprises. The public interest and health groups will favor some restrictions on current practices; the broadcasters and advertisers will oppose any rule-making. The arguments for both sides are also fairly predictable—the health and well-being of children versus the free enterprise system and the First Amendment rights of the advertisers.

The Advertising Process

Like most adults, I have become inured to the commercial-saturated world of television, but, apart from the usual moments of pique, I have never considered seriously what is involved in the whole process of advertising aimed directly at children.

Let's return to the ad quoted at the outset. It represents the whole process in microcosm: sell to the parents by convincing the children. The sophisticated techniques of advertising are put in the service of psychologically enticing children to want something so much that they will persuade their parents to buy it. Quite apart from the question of the real value of the advertised product, what is the propriety of the sponsor contesting the parent for control of the child? When the products are harmful to the child's well-being, the process is insidious. Very young children are gullible and unsophisticated; they cannot make sound judgments about the quality of what is being sold to them.

The advertisers challen[illegible]his charge by arguing that parents have ultimate control at the point of purchase. This is hardly an adequate justification for enticing children into wanting things that are bad for them. And even with products that may be good for them, it seems like an unwarranted intrusion. Parents have enough difficulty in helping their children to make wise choices without skewing the process by 500 million dollars worth of counter-persuasion.

Where does the responsibility lie for regulating children's exposure to television commercials? Advertisers, regulatory agencies, and consumers all should bear some of the burden.

Advertisers and Broadcasters

William La Mothe, the president of Kellogg Foods, states the argument for the advertisers: "Once we start deciding which group can be advertised to and which group cannot, advertising as an efficient and economic method will be on its way to oblivion."

Peggy Charren of Action for Children's Television (ACT) counters with an attack on the quality of what is being advertised: "The two things sold to children most on TV are toys and food, and we've found that 98 percent of the food advertising is for products children don't have to eat, non-nutritive things. Now in fact they're designing foods that would never be on the market if it weren't for television and its ability to sell them. They actually design junk cereals like Frankenberry and Cocoa Pebbles and Cookie Crisps because they can push them to kids on television."

Jean Mayer, the well-known nutritionist and president of Tufts University, advances as a rough rule of thumb: the nutritional value of a food varies inversely with the amount of money spent to advertise it. Research confirms that the most heavily advertised foods are the ones asked for most often. One study concludes that parents accede to these requests 87 percent of the time. And this all takes place in an environment where the average child sees five hours of commercials per week and a total of 25,000 commercials per year. Richard Feinbloom of Harvard Medical School finds this an unfair use of selling techniques. "An advertisement to a child has the quality of an order, not a suggestion. The

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child lacks the ability to set priorities, to determine relative importance and to reject some directions as inappropriate."

The industry contends that advertisements are protected by the First Amendment. And if appeals to freedom of speech will not settle the argument, they remind us that ad revenues pay for the programs. Their cries of constitutional rights ignore the ample precedents for limiting free speech when the issue affects children. It is true the ads support the programs, but some people argue that it would be just fine if most of those shows went away; others urge more public funding for children's programming; others contend that if the junk were eliminated from the ad content, there would still be enough good products to meet program budgets.

Regulatory Agencies

While the advertisers have $500,000,000 in their budget for children's advertising, the public interest groups have difficulty in getting their combined budgets up to $500,000. The battle is so unequal that federal regulatory agencies have a responsibility to act on behalf of the interests of children and parents. The self-regulation favored by the broadcasters and the advertisers does not work. They have had to be forced to accept almost all the limitations put on their activities up to this point. Right now they are organizing a massive campaign to oppose the FTC proposals.

No other country in the world allows

Research on Young Viewers: The Policy Implications

Is television advertising good or bad for children? Opinions are firm on both sides of the question, but what evidence exists to support either view? Academic research on the effects of television advertising on children is relatively recent, and few investigators have been specifically concerned with the field. Still, according to a recent report by the RANN (Research Applied to National Needs) Program of the National Science Foundation, the current state of knowledge, though inadequate in many areas, is "sufficient in others to provide meaningful guidance to policymakers."

The report, *Research on the Effects of Television Advertising on Children* (Washington: National Science Foundation, 1977) is a review of the literature and gives recommendations for future research. Two major conclusions emerge from the review. First, "It is clear from the available evidence that television advertising *does* influence children." Children can and do learn from commercials, and advertising is at least moderately successful in creating positive attitudes toward and a desire for certain products. The most significant variable that determines the child's perception of television advertising is age. Numerous studies have demonstrated that as children grow older, they become more skillful in discriminating among commercial messages and are less easily persuaded by the sponsor's sales pitch. One study of fourth- through seventh-graders in Michigan showed that less than one-quarter think that commercials always tell the truth. Most of the children were also irritated by the commercial interruptions.

The second conclusion is that "From a policy standpoint, the most immediately relevant research is that which either documents the effects of specific advertising practices alleged to be misleading or unfair to children's perceptions, or which tests the efficacy of regulatory provisions in preventing such abuses." Several recent studies have shown, for example, that the way in which a disclaimer is worded and presented ("some assembly required" or "batteries not included") affects the child's ability to understand and remember the message.

In reviewing the research, the report focused on ten issues that seemed to be of greatest interest to the parties involved, were amenable to empirical testing, and offered some prospects of concrete policy action based on empirical findings. These included:

1. Children's ability to distinguish television commercials from program material;
2. The influence of format and audiovisual techniques on children's perceptions of commercial messages;
3. Self-concept appeals in advertising;
4. The effects of advertising containing premium offers;
5. The effects of violence or unsafe acts in commercials;
6. The impact of proprietary medicine advertising;
7. The effects of television food advertising;
8. The effects of volume and repetition of commercials;
9. The impact of advertising on consumer socialization; and
10. The effect on parent-child relations.

In most of these areas the research findings are only suggestive. For instance, there is evidence that television food advertising to children is generally effective. However, there is no evidence directly linking food commercials to the nutritional status of children, nor to the claim that food advertising messages encourage children to use nutritionally irrelevant criteria in making food choices. An even broader value question is whether food advertisers should be responsible for communicating nutritional information beyond that pertaining to their own products.

In the future, the report concludes, research must be directed more closely to policy needs. Nevertheless, research is only one element in determining policy and practice. Ethical, legal, economic, and political considerations must all play a part. Adequate safeguards for young viewers must be based on both a solid understanding of what television does and does not do and a basic conception of what kind of consumers and citizens we want to encourage children to become.

—Carol Levine

such blatant exploitation of its children for commercial purposes. Australia, Canada, and the United Kingdom are in the process of further limiting and refining their already strict standards and practices for children's advertising. If, as we often are reminded, children are our most important natural resources, then it is perfectly legitimate for the appropriate federal agencies to protect that resource from any harm. The process which is now beginning at the FTC will provide a visible forum for the public discussion of these issues over the next year. The staff recommendations on the public comments must be submitted to the Commission members by April 1979.

Parents and Teachers

Most of the debate before the FTC will legitimately focus on the rights and obligations of the broadcasters and advertisers. But parents and the schools also have responsibilities, which are not fully discharged by merely cataloging and taking action against the abuses of the producers. Even the best of all possible programming does not justify the four hours a day spent by the average American in front of the TV set. In our less-than-perfect world, the uncomfortable fact is that we have to reform ourselves as well as the networks.

Action for Children's Television has been the most persistent and persuasive advocacy group in the field. ACT filed one of two petitions to which the FTC formally responded in its recommendations, the other was filed by the Center for Science in the Public Interest. In addition to its effort to keep the issue of children and television before the FCC and the FTC, ACT has also encouraged parents to become more involved in controlling their children's viewing and in discussing television with them. ACT is currently distributing a red tag to be affixed to the family television set. It reads, "REMINDER: Too much television can be harmful to your child." The FCC and the FTC can only help to remove the abuses. Parents, teachers, and other adults have the responsibility to help children develop informed and disciplined choices about what images go into their heads and what foods go into their stomachs.

It has always made good sense for people who live on water to learn how to swim. Despite the recent suggestions of authors like Marie Winn in *The Plug-In Drug* and Jerry Mander in *Four Arguments For the Elimination of Television* arguing that TV should be banished from children's lives, television programs and commercials are not going to go away. And the so-called children's programs constitute only 15 percent of the average child's viewing diet. Cleaning up the Saturday morning "kid-vid ghetto" is only a small part of the enterprise. All television watched by children becomes children's television.

Early in May a House appropriations subcommittee voted five to four to bar the FTC from spending money to develop trade rules that would limit advertising for any food product whose ingredients have been designated as safe by the FDA. This provision, if approved by the full Appropriations Committee, would prevent the FTC from carrying out its planned inquiry on children's television advertising. The provision was sponsored by Mark Andrews (R.-N.D.), whose constituents include many corn, wheat, and sugar-beet growers.

In the media environment, it is no longer possible to protect children from the outside. We must provide them with habits of judgment, taste, and selectivity which will enable them to be their own TV critics and consumer guides. This is already being done in many schools where teachers discuss programs and commercials which are part of the child's ordinary viewing experience. The process helps to unpack the glut of vicarious experiences which builds up within the child.

By stimulating and informing the students' responses to television the schools can induce a critical and knowledgeable attitude toward future viewing. In many schools students also actually work with TV, film, and photographic equipment to make their own images and personal statements. This process initates them to the myriad choices and critical judgments involved in establishing the mood, pace, and tone of any media production. The goals for the student in such programs of media criticism and production can be stated quite simply:

Smart is better than stupid.
Active is better than passive.

The Future

Winston Churchill has said: "We shape our buildings and thereafter they shape us." So with our television system. During the 1940s the United States opted for a limited-spectrum, commercially supported TV system. Once such a system is in place, it takes massive efforts to produce minimal reforms; the attempt to regulate children's advertising is a good example.

The technology of the future is now being set in place. There will be multiple (up to 100) channel systems, with recording and playback capacity, with dial-access potential allowing consumers to request specific programs, with large screens and direct or indirect satellite linkups.

The new television system will make it possible to serve the television needs of audiences in numbers far less than the 20 to 30 million people now required by network television. The new system will give us a way to let people pay for what they want. It will provide television with a turnstile and allow consumers to make direct choices as they do for books, films, and plays.

Two areas of reform that we can think about now, which cost nothing, and which make everything possible, are: (1) both cable and satellite systems should be required to allocate several channels and/or percentages of time for quality children's programming, and (2) a percentage of the taxes collected from television revenues should be earmarked for these same purposes.

Even "ideal" television, however does not guarantee an ideal world. We often overestimate the medium's power for good as well as for harm. There is life after (and before) television, and it is the quality of that life that probably most determines the impact of television on children. Those who are alert and alive to their own bodies, emotions, and minds and whose lives are caught up in activities with others won't make the networks and the sponsors rich. Living well is still the best revenge and the best protection.

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NOTE

CAN'T GET ENOUGH OF THAT SUGAR CRISP: THE FIRST AMENDMENT RIGHT TO ADVERTISE TO CHILDREN

Introduction

On April 27, 1978, the Federal Trade Commission published proposed rules which may virtually eliminate commercial television advertising directed at young children.[1] The proposals would lead to the promulgation of final regulations by 1980,[2] and are part of the latest round of governmental efforts to deal with the effects of television advertising on young audiences. Since 1970, the FCC,[3]

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[1] Children's Advertising, Proposed Trade Regulation Rulemaking and Public Hearing, 43 Fed. Reg. 17967 (1978) [hereinafter Children's Advertising Proposals].

[2] *See* Conference Comm. on Appropriations for Departments of State, Justice, Commerce, Judiciary, and Related Agencies, Conference Report, H.R. Rep. No. 1565, 95th Cong., 2d Sess. 24 (1978) [hereinafter Conference Report].

[3] Notice of Inquiry and Notice of Proposed Rule Making *In re* Action for Children's Television, 36 Fed. Reg. 1429, 28 F.C.C.2d 368 (1971) [hereinafter 1971 Notice of Inquiry]. Action for Children's Television (ACT) filed a petition in 1970 which requested the FCC to ban sponsorship of and commercials on children's programming and to require stations to broadcast at least 14 hours per week of programs for children. In 1974, however, the FCC rejected ACT's proposal. Children's Television Report and Policy Statement, 39 Fed. Reg. 39395, 39397-400, 50 F.C.C.2d 1, 6-12 (1974), *reconsideration denied*, 55 F.C.C.2d 691 (1975), *aff'd sub nom.* Action for Children's Television v. FCC, 564 F.2d 458 (D.C. Cir. 1977) [hereinafter Children's Television Report]. The FCC recognized the seriousness of the controversy surrounding the "overcommercialization" of children's television, but refused directly to impose government sanctions, endorsing instead "voluntary" industry measures that would reduce the amount of advertising directed at children and curtail advertising practices regarded as deceptive. Those individuals refusing to comply with the "voluntary" controls would be required to justify their actions to the Commission. *Id.* at 39399-402, 50 F.C.C.2d at 9-19. In August 1978, the FCC announced that it was reopening its inquiry into children's television, and invited comments on the effects of its 1974 opinion. Second Notice of Inquiry, 43 Fed. Reg. 37136, 68 F.C.C.2d 1074 (1978).

Although the FCC has primary responsibility for overseeing the use of the airwaves, it has delegated its authority to regulate unfair or deceptive broadcast advertising to the FTC. Liaison Agreement Between Federal Communications Commission and the Federal Trade Commission, 3 Trade Reg. Rep. (CCH) ¶ 9852 (issued Apr. 27, 1972), *noted in* 34 F.C.C.2d 1120 (1972). Under the agreement, the FTC has "primary jurisdiction over all matters regulating unfair or deceptive advertising in all media." *Id.* The FCC has not, however, wholly abrogated its responsibility toward advertising, and "will continue to take into account pertinent considerations" relating to advertising practices in making licensing decisions. *Id.* The FCC recognized, through the policy outlined in the Liaison Agreement that the FTC has the expertise to evaluate advertising, and that FTC remedies which are not available to the FCC, including the power to ban advertising, may provide more appropriate remedies for deceptive and misleading advertisng than the licensing authority of the FCC. *See* Note, *Fairness and Unfairness in Television Product Advertising*, 76 Mich. L. Rev. 498, 521-22 (1978) [hereinafter Note, *Fairness and Unfair-*

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the FTC,[4] Congress,[5] the courts,[6] and well over 100,000 private citizens[7] have participated in the debate over broadcast advertising directed at children. The difficult conflict between the government's power to regulate commercial speech and the first amendment rights of advertisers and broadcasters will undoubtedly be resolved in the courts.

The FTC has proposed to:

> (a) Ban all televised advertising for any product which is directed to, or seen by, audiences composed of a significant proportion of children who are too young to understand the selling purpose of or otherwise comprehend or evaluate the advertising;
>
> (b) Ban televised advertising for sugared food products directed to, or seen by, audiences composed of a significant proportion of older children, the consumption of which product poses the most serious dental health risks;

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ness], Handling of Public Issues Under the Fairness Doctrine and the Public Interest Standard of the Communications Act, 39 Fed. Reg. 26372, 26382, 48 F.C.C.2d 1, 27-28 (1974), *reconsideration denied*, 58 F.C.C.2d 691 (1976), *aff'd mem. sub nom.* National Citizens Comm. for Broadcasting v. FCC, 559 F.2d 187 (D.C. Cir. 1977).

[4] In 1977, the FTC considered and rejected a proposal that would have banned advertising of "premiums"—*i.e.*, inducements such as toys included in cereal boxes, which are designed to make the products more desirable—to children. Advertising of Children's Premiums on Television, Rejection of Proposed Guide, 42 Fed. Reg. 15069 (1977) [hereinafter Premium Report]. In so doing, the FTC acknowledged the "evidence . . . concerning the vulnerability of children to television advertising" and announced that it would continue to closely monitor children's advertising on a case-by-case basis. *Id.* at 15072; *see* text accompanying note 125 *infra*. In addition, FTC rulings on specific advertisements have noted children's alleged special vulnerability to advertised messages. *See, e.g.*, ITT Continental Baking Co. v. FTC, 532 F.2d 207, 214 (2d Cir. 1976), Hudson Pharmaceutical Corp., 89 F.T.C. 82, 86 (1977). For a discussion of the FTC's involvement with children's advertising, see Thain, *Suffer the Hucksters to Come Unto the Little Children? Possible Restrictions of Television Advertising to Children Under Section 5 of the Federal Trade Commission Act*, 56 B.U.L. REV. 651, 661-64 (1976).

[5] *See Hearings on Broadcast Advertising and Children Before the Subcomm. on Communications of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 1st Sess. (1975); *Hearings on Nutrition Education, Part 3—TV Advertising of Food to Children Before the Senate Select Comm. on Nutrition and Human Needs*, 93d Cong., 1st Sess. (1973); *Hearings on Dry Cereal Before the Consumer Subcomm. of the Senate Commerce Comm.*, 91st Cong., 1st Sess. (1970).

[6] Action for Children's Television v. FCC, 564 F.2d 458, 461 (D.C. Cir. 1977), *aff'g* Children's Television Report, *supra* note 3, 50 F.C.C.2d 1. The judiciary reentered the controversy in November 1978, when the District Court for the District of Columbia ruled that FTC Chairman Michael Pertschuk could not participate in the proposed rulemaking on children's advertising because his public statements evinced a clear prejudice in favor of the proposed ban. Association of Nat'l Advertisers v. FTC, 460 F. Supp. 996, 998 (D.D.C. 1978).

[7] The FCC reported the receipt of over 100,000 comments from private individuals and citizens' groups during its initial proceedings on the ACT petition. "This material falls into three main categories: formal pleadings, programming data from stations and networks, and informal expressions of opinion (letters and cards)." Children's Television Report, *supra* note 3, at 39396, 50 F.C.C.2d at 2; *see id.* at 39402-04, 50 F.C.C.2d at 19-24 (summary of comments).

> (c) Require televised advertising for sugared food products not included in Paragraph (b), which is directed to, or seen by, audiences composed of a significant proportion of older children, to be balanced by nutritional and/or health disclosures funded by advertisers.[8]

In justifying these proposals, the FTC Staff Report on Television Advertising to Children[9] asserted that television advertising directed at viewers under the age of eight[10] exploits an audience that does not comprehend the selling purpose of commercial advertisements[11] and is more trusting and naive than adults are. Accordingly, the FTC staff contended that all advertisements seen by small children are inherently deceptive and unfair, and therefore should be removed from the air pursuant to the FTC's statutory authority to eliminate unfair business practices.[12]

The Staff Report also argued that the advertising of sugared products poses a health risk to all children, because such products promote tooth decay and create bad childhood eating habits that may result in obesity and other diseases later in life.[13] Relying on its statutory authority to regulate as deceptive[14] those advertisements that fail to reveal significant health risks, and on its claimed authority to ban "unfair" advertising which harms consumers, the FTC concluded that televised advertisements for highly sugared foods should also be banned.[15]

Since the ban on children's television advertising was first proposed,[16] the FCC,[17] three congressional committees,[18] and a federal court[19] have questioned whether such a ban is constitutionally permissible. Undoubtedly, televised advertising directed at small children is unpopular,[20] but the first amendment was designed to protect unpopular speech from government censorship.[21] The exception of commercial advertising from first amendment protection, originally relied upon by those arguing for the constitutionality of the proposed ban,[22] has recently been replaced by the far less determinate doctrine of commercial speech, which does extend some constitutional recognition to the right to advertise.[23] Hence, even commercial speech must be presumed worthwhile, and those who would ban it must provide proof that it must be banned in the public interest, rather than mere allegations of unpopularity.

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[8] Children's Advertising Proposals, *supra* note 1, at 17969.

[9] FTC Staff Report on Television Advertising to Children (Feb. 1978) (unpublished report on file at *New York University Law Review*) [hereinafter FTC Staff Report]. The report is a proposal to the FTC by its professional staff. After public hearings, the FTC will decide whether to adopt, modify, or reject the regulations recommended by the staff. Children's Advertising Proposals, *supra* note 1, at 17967.

[10] FTC Staff Report, *supra* note 9, at 10 n.16. The FTC staff is imprecise about the exact age at which the "cut off" of advertising should take place, and invites comments on the question whether there is "a specific age below which significant numbers of children are unable to understand . . . advertising." Children's Advertising Proposals, *supra* note 1, at 17969.

[11] FTC Staff Report, *supra* note 9, at 82-104, 328-31.

[12] *Id.* at 221-29.

[13] *Id.* at 18-21, 158-72.

[14] 15 U.S.C. §§ 45(a), 52(b) (1976); *see* FTC Staff Report, *supra* note 9, at 175-218.

[15] FTC Staff Report, *supra* note 9, at 331-33.

[16] *See* note 3 *supra*.

[17] 1971 Notice of Inquiry, *supra* note 3, at 1429, 28 F.C.C.2d at 369-70.

[18] In voting funds for FTC operations during fiscal 1978, the Senate and House Appropriations Committees and a Senate-House Conference Committee expressed concern over the propriety and constitutionality of the proposed rulemaking and promised a congressional inquiry

The constitutional issues are more difficult because of the strong policy considerations on each side of the debate over television commercials and children. On one hand, the first amendment should not be used as a talisman for the protection of corporate profits against legitimate regulations that are necessary to safeguard the nation's children. However, if the Constitution shelters all who wish to promote their products legally and truthfully, then government suppression, even in the name of protection, must overcome a strong presumption of unconstitutionality.[24] This Note examines the proposed ban on children's advertising in light of recent developments in the constitutional doctrine of commercial free speech. It concludes that the proposed regulations are overly broad and, therefore, unconstitutional.

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into any rulemaking on advertising directed at children. CONFERENCE REPORT, *supra* note 2, at 24; SENATE APPROPRIATIONS COMM., DEPARTMENTS OF STATE, JUSTICE, AND COMMERCE, THE JUDICIARY, AND RELATED AGENCIES APPROPRIATION BILL, 1979, REPORT, S. REP. NO. 1043, 95th Cong., 2d Sess. 72-73 (1978); HOUSE COMM. ON APPROPRIATIONS, DEPARTMENTS OF STATE, JUSTICE, AND COMMERCE, THE JUDICIARY, AND RELATED AGENCIES APPROPRIATION BILL, FISCAL YEAR 1979, REPORT, H.R. REP. NO. 1253, 95th Cong., 2d Sess. 46 (1978).

[19] Action for Children's Television v. FCC, 564 F.2d 458, 480 (D.C. Cir. 1977).

[20] Children's Television Report, *supra* note 3, at 39407, 50 F.C.C.2d at 29-31; NATIONAL SCIENCE FOUNDATION, RESEARCH ON THE EFFECTS OF TELEVISION ADVERTISING ON CHILDREN 134-36 (1978) [hereinafter NSF RESEARCH]; *see* Thain, *supra* note 4, at 651-54; Note, *Unsafe for Little Ears? The Regulation of Broadcast Advertising to Children*, 25 U.C.L.A. L. REV. 1131, 1131-34 (1978) [hereinafter Note, *Little Ears*].

[21] Lovell v. Griffin, 303 U.S. 444, 451-52 (1938).

[22] Children's Television Report, *supra* note 3, at 39399, 50 F.C.C.2d at 10-11; Children's Programming Inquiry 15-16, 25-26, Action for Children's Television, F.C.C. Docket No. 19142 (staff report filed Aug. 20, 1971) [hereinafter Children's Programming Inquiry].

[23] *See* text accompanying notes 25-55 *infra*.

[24] As Judge Skelly Wright argued in dissent from the decision upholding the federal law banning television advertising for cigarettes:

> This is not an ordinary "free speech" case. It involves expression which is ostensibly apolitical, advocating a particularly noxious habit through a medium which the Government

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THE FIRST AMENDMENT AND THE RIGHT TO ADVERTISE

A. *The Emergence of the Right*

Until recently, commercial advertisements were deemed outside the scope of first amendment protection: following the Supreme Court's 1942 decision in *Valentine v. Chrestensen*,[25] most courts held that speech which merely proposed a commercial transaction could be regulated without the presumption of illegality which attaches to regulation of purportedly higher forms of speech.[26] The courts upheld statutes regulating—and even banning—speech of a purely commercial nature, statutes that clearly would have been impermissible had the speech been outside the realm of commerce.[27] When the Supreme Court invalidated regulation of advertising, it was forced to find some element elevating the regulated speech to a level more closely guarded by the Constitution.[28]

But in 1976 the Supreme Court overruled *Valentine* and its progeny when it invalidated a state ban on the advertising of prescription

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> has traditionally regulated more extensively than other modes of communication. But the unconventional aspects of the problem should not distract us from the basic First Amendment principles involved. Any statute which suppresses speech over any medium for any purpose begins with a presumption against its validity.

Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582, 590 (D.D.C. 1971) (Wright, J., dissenting), *aff'd mem. sub nom.* Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972).

[25] 316 U.S. 52 (1942).

[26] *E.g.*, United States v. Hunter, 459 F.2d 205, 211-12 (4th Cir.), *cert. denied*, 409 U.S. 934 (1972); Wulp v. Corcoran, 454 F.2d 826, 834 n.13 (1st Cir. 1972) (dictum); SEC v. Texas Gulf Sulfur Co., 446 F.2d 1301, 1305-06 (2d Cir.), *cert. denied*, 404 U.S. 1005 (1971); Banzhaf v. FCC, 405 F.2d 1082, 1101-02 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969); Wolfe v. City of Albany, 189 F. Supp. 217, 221 (M.D. Ga. 1960) (dictum); Comment, *First Amendment Protection for Commercial Advertising: The New Constitutional Doctrine*, 44 U. CHI. L. REV. 205, 205 (1976) [hereinafter Comment, *The New Constitutional Doctrine*]. *But see* George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 424 F.2d 25, 33-34 (1st Cir.), *cert. denied*, 400 U.S. 850 (1970) (suggesting that speech purely commercial in nature is entitled to some degree of constitutional protection).

[27] *E.g.*, Pittsburgh Press Co. v. Human Relations Comm., 413 U.S. 376, 387-89 (1973) (upholding a local prohibition of gender-based classifications in want-ads); Breard v. Alexandria, 341 U.S. 622, 641-45 (1955) (upholding local "Green River" ordinance banning door-to-door magazine sales); Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582, 584-85 (D.D.C. 1971) (affirming broadcaster's rights, but upholding congressional ban on television and radio cigarette advertising), *aff'd mem. sub nom.* Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972).

[28] *See* Bigelow v. Virginia, 421 U.S. 809, 821-25 (1975) (striking down a ban on abortion advertising which was not purely commercial but also conveyed information of public interest).

drug prices. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,[29] Justice Blackmun's majority opinion flatly rejected the "simplistic approach"[30] of the *Valentine* doctrine, and held for the first time that purely commercial advertisements are not devoid of constitutional protection.[31] The Court reasoned that society has an interest in the free flow of commercial information;[32] accordingly, the Court held that, in this case, the government could not "completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients."[33]

In rejecting the absolutist approach of *Valentine*, the Court implicitly endorsed for commercial speech the balancing test set out in *Bigelow v. Virginia*,[34] which "assess[es] the First Amendment interest at stake and weigh[s] it against the public interest allegedly served by the regulation."[35] In *Virginia Pharmacy*, the Court found that the public interest in ready access to drug price information easily outweighed Virginia's stated purpose of avoiding the lowered professional standards among pharmacists that might result from advertising and competition.[36]

Although the Court observed that a consumer's interest in commercial information may be even greater than his interest in the political debates of the day,[37] the Court did not elevate commercial speech to the same level of protection as that enjoyed by political expression. Concluding that purely commercial speech is "hardier" in that the advertiser's profit motive will militate against any chilling effect of regulation, and that commercial speech is more readily subjected to empirical testing for truthfulness,[38] the Court declared that such advertising could constitutionally be regulated to ensure that

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[29] 425 U.S. 748 (1976).

[30] *Id.* at 759.

[31] *Id.* at 762, 770.

[32] *Id.* at 763-65.

[33] *Id.* at 773. The Court explicitly limited this holding to the narrow situation before it, *i.e.*, the regulation of commercial advertising by pharmacists. The Court noted that other forms of commercial speech regulation, including the "special problems of the electronic broadcast media," *id.*, were not at issue. *Id.* at 770-73 & n.25.

[34] 421 U.S. 809 (1975).

[35] *Id.* at 826; *see* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 762-70.

[36] 425 U.S. at 762-70.

[37] *Id.* at 763.

[38] *Id.* at 771 n.24.

"the stream of commercial information flow[s] cleanly as well as freely."[39]

Since 1976, the Supreme Court has employed the *Virginia Pharmacy* doctrine to strike down state and municipal bans on advertising by lawyers,[40] advertisement and in-store displays of contraceptive products,[41] and real estate "for sale" signs.[42] In addition, lower courts have used the commercial speech doctrine to restrict FTC regulation of both published and broadcast advertisements;[43] and several courts have held that FTC rules prohibiting deceptive advertisements must be carefully and narrowly drafted to effect government policy with the least possible impact on advertisers' legitimate right to promote their products truthfully.[44] The Supreme Court has not yet considered a case involving federal regulation of advertising or the "special problems of advertising on the electronic broadcast media"[45] raised by the proposed FTC rulemaking. As one former FTC Commissioner has noted, "the Supreme Court [has not] come within miles of considering and deciding the novel issues of children's advertising now before the Commission."[46]

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[39] *Id.* at 772, *accord*, Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 454-55 (1978); Bates v. State Bar of Ariz., 433 U.S. 350, 380-81 (1977). The notion that different types of protected speech may warrant different levels of protection is consistent with the Court's more explicit rulings concerning non-obscene but sexually explicit speech. *See* FCC v. Pacifica Foundation, 438 U.S. 726, 744-48 (1978) ("offensive" words have low social value, and therefore may be regulated in certain contexts); Young v. American Mini Theatres, Inc., 427 U.S. 50, 68-73 (1976) (plurality opinion) (the lower first amendment value of sexually explicit films warrants zoning restrictions that might not be placed on theaters showing inoffensive films).

[40] Bates v. State Bar of Ariz., 433 U.S. 350, 365 (1977). *But see* Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 454-68 (1978) (upholding state sanctions on direct solicitation of clients by attorneys); *cf.* Friedman v. Rogers, 99 S. Ct. 887, 893-97 (1979) (upholding a Texas law which barred the use of trade names by optometrists).

[41] Carey v. Population Servs. Int'l, 431 U.S. 678, 700-02 (1977).

[42] Linmark Assocs., Inc. v. Township of Willingboro, 431 U.S. 85, 97 (1977).

[43] Standard Oil of Cal. v. FTC, 577 F.2d 653, 662-63 (9th Cir. 1978) (rejecting as overbroad an FTC order that company cease and desist from any advertising that might be misleading, since such prohibition could discourage truthful advertising as well); National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977) (acknowledging FTC regulatory authority but rejecting as overbroad an FTC requirement that egg industry disclose scientific concern over relationship between egg consumption and circulatory disease), *cert. denied*, 99 S. Ct. 86 (1978).

[44] Standard Oil Co. of Cal. v. FTC, 577 F.2d 653, 662 (9th Cir. 1978); National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977), *cert. denied*, 99 S. Ct. 86 (1978); Warner-Lambert Co. v. FTC, 562 F.2d 749, 758-63 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978); Beneficial Corp. v. FTC, 542 F.2d 611, 618-20 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977); *cf.* FTC v. Simeon Management Corp., 532 F.2d 706, 713, 717 (9th Cir. 1976) (order mandating corrective advertising based on mere reasonable belief of advertisement's falsity was insufficient to protect advertiser's first amendment rights). *Compare* Comment, *The Right to Receive and the Commercial Speech Doctrine: New Constitutional Considerations*, 63 GEO. L.J. 775, 802 (1975) [hereinafter Comment, *The Right to Receive*] *with* Recent Development, *First Amendment Restrictions on the FTC's Regulation of Advertising*, 31 VAND. L. REV. 349, 371-73 (1978) (arguing for broader FTC discretion) [hereinafter Recent Development, *First Amendment Restrictions*].

B. *The Right to Advertise to Children*

The FTC Staff Report asserted that advertising directed at children is entitled to no constitutional protection under the balancing test employed by the Supreme Court in *Virginia Pharmacy*.[47] The report contended that the Court's only rationale for extending protection to commercial speech was the finding that such speech contributes to rational decisionmaking in the marketplace.[48] Therefore, since children lack full capacity for reasoned decisionmaking,[49] and since young children do not comprehend the commercial motivations of the marketplace,[50] constitutional protection for advertising directed at young audiences is not justified.[51] By focusing on only one aspect of the *Virginia Pharmacy* opinion, this analysis fails to recognize the myriad of first amendment considerations surrounding the question of advertising and children. This section will discuss those considerations, and argue that the proposed advertising ban violates the first amendment rights of advertisers, children, and broadcasters.

1. *The Rights of Advertisers*

Although the issue of the rights of advertisers was not directly raised by the *Virginia Pharmacy* case,[52] the protection of these interests is an essential element of the Court's opinion. Conceding that an advertiser's commercial speech interests are "purely economic," the Court nevertheless held that his financial concern "hardly disqualifies him from protection under the First Amendment."[53] According to the Court, by promoting freely competing businesses, advertising helps to ensure the best general allocation of resources and is an "indispensable" component of the free enterprise system.[54] This reasoning suggests that the interest of society parallels the interest of the commercial advertisers. The Staff Report failed to recognize this aspect of *Virginia Pharmacy*[55] and thus ignored the rationale underlying the protection afforded to free speech in the marketplace.

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[45] Bates v. State Bar of Ariz., 433 U.S. 350, 384 (1977); *see* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 773; Note, *Fairness and Unfairness*, *supra* note 3, at 543-45.

[46] Letter from former FTC Commissioner Philip Elman to FTC Chairman Michael Pertschuk (Feb. 17, 1978) (on file at *New York University Law Review*) [hereinafter Elman Letter].

[47] FTC Staff Report, *supra* note 9, at 255-67.

[48] *Id.* at 258-60.

[49] *See* Ginsberg v. New York, 390 U.S. 629, 649 (1968) (Stewart, J., concurring) (state may determine that children lack full capacity for individual choice, "at least in some precisely delineated areas").

[50] *See* text accompanying note 125 *infra*.

[51] FTC Staff Report, *supra* note 9, at 237, 255-67.

[52] 425 U.S. at 753. The plaintiffs in *Virginia Pharmacy* were not advertisers, but consumers who claimed a right to product information. *Id.*

2. *The Rights of Children*

In the proposed rulemaking, the FTC staff argued that while commercial information might be important for adults, "it is unreasonable to assume that very young children are able rationally to understand and evaluate conflicting or potentially harmful commercial messages."[56] But the FTC staff's assumption that children therefore have no right to receive commercial information is inconsistent with prior case law. The Supreme Court has ruled repeatedly that children are entitled to constitutional protection,[57] although speech directed at children may be subject to stricter governmental control than is speech directed only at adults.[58] Specifically, the Court has held that "minors are entitled to a significant measure of First Amendment protection, . . . and only in relatively narrow and well-defined circumstances may government bar public dissemination of protected materials to them."[59] The Court has struck down limitations on the constitutional rights of children, when such restrictions were not reasonable and necessary to protect the health, morals, or welfare of the children.[60]

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[53] *Id.* at 762.

[54] *Id.* at 765; *see* Bates v. State Bar of Ariz., 433 U.S. 350, 364 (1977); Dun & Bradstreet, Inc. v. Grove, 404 U.S. 898, 905-06 (1971) (Douglas, J., dissenting from denial of certiorari); FTC v. Procter & Gamble Co., 386 U.S. 568, 603-04 (1967) (Harlan, J., concurring). One commentator has observed that *Virginia Pharmacy* protects commercial speech only to the extent that the speech "indirectly contributes to the ends traditionally served by the first amendment by supplying the public with information, images and values that may enter into the discussion of public issues and the creation of works of artistic expression." Comment, *The New Constitutional Doctrine*, *supra* note 26, at 226-27. That view, however, appears to be wholly inconsistent with the language in *Virginia Pharmacy* distinguishing that case from Bigelow v. Virginia, 421 U.S. 809 (1975). In *Bigelow*, the Court had found it dispositive that the challenged advertisement discussed the availability of abortion services, an issue of significance beyond the realm of commerce. *Id.* at 821-22; *see Virginia Pharmacy*, 425 U.S. at 759-61. In contrast, the *Virginia Pharmacy* opinion explicitly stated:

> Our pharmacist does not wish to editorialize on any subject, cultural, philosophical, or political. He does not wish to report any particularly newsworthy fact, or to make generalized observations even about commercial matters. The "idea" he wishes to communicate is simply this: "I will sell you the X prescription drug at the Y price."

Id. at 761.

[55] FTC Staff Report, *supra* note 9, at 260-64.

[56] *Id.* at 260.

[57] Planned Parenthood of Mo. v. Danforth, 428 U.S. 52, 74-75 (1976) (minors' right to abortions without parental consent); Tinker v. Des Moines Independent Community School Dist., 393 U.S. 503, 505-14 (1969) (students' right to freedom of expression in public schools); *In re* Gault, 387 U.S. 1, 12-31 (1967) (juveniles' right to due process); *see* Geiser, *The Rights of Children*, 28 HASTINGS L.J. 1027, 1034 (1977) (suggesting that the federal courts are broadening their recognition of children's rights).

Because children have some constitutional right to information, then, the government may not suppress commercial speech directed at them absent a showing of harm compelling enough to overcome the presumption of unconstitutionality that normally faces limitations on protected speech.[61] To the extent that the FTC can establish that advertising takes unfair advantage of the particular weaknesses of children, the FTC may be able to curtail such advertising. The degree to which the evidence against children's advertising might justify such a curtailment of rights will be considered in section II.[62]

3. *The Rights of Broadcasters and Program Content*

In the case of televised commercials, the rights of broadcasters must also be considered. The Supreme Court has ruled that radio and television broadcasters are protected by the first amendment,[63] although it is the first amendment rights of listeners that are paramount.[64] Now that the Court has recognized that commercial speech is entitled to constitutional protection,[65] the first amendment rights of broadcasters, too, are implicated whenever their power to air any particular advertisement is regulated.[66]

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[58] FCC v. Pacifica Foundation, 438 U.S. 726, 749-50 (1978) (FCC can prohibit indecent radio broadcast to protect children in listening audience); Ginsberg v. New York, 390 U.S. 629, 638 (1968) (state's authority to regulate the sale of obscene literature is greater when minors are involved) (citing Prince v. Massachusetts, 321 U.S. 158, 170 (1944)); *cf.* Butler v. Michigan, 352 U.S. 380, 383-84 (1957) (statute barring all sales of materials deemed unfit for children violated due process rights of adults to whom materials were not obscene).

[59] Erznoznik v. City of Jacksonville, 422 U.S. 205, 212-13 (1975) (citation omitted).

[60] *Id.* at 212-14 (ordinance preventing drive-in movie theaters from exhibiting films containing nudity struck down as overbroad); Tinker v. Des Moines Independent Community School Dist., 393 U.S. 503, 509 (1969) (regulation forbidding students from wearing armbands to school struck down as unreasonable); ***see*** Prince v. Massachusetts, 321 U.S. 158, 174 (1944) (Murphy, J., dissenting). It has been argued that the relatively recent "child pornography" cases stand for the broad proposition that regulators have a virtually unfettered right to determine what children may see and hear. *See* FTC Staff Report, ***supra*** note 9, at 243-49. It should be noted, however, that sexually explicit speech may enjoy less first amendment protection than does other speech: while the Court has repeatedly ruled that listeners may not be insulated from ideas that they might find offensive, *e.g.*, Carey v. Population Servs. Int'l, 431 U.S. 678, 701 (1977); Cohen v. California, 403 U.S. 15, 21 (1971), censorship of pornography has been allowed even without a showing of harmfulness in the interest of protecting "the sensibilities of unwilling recipients." Miller v. California, 413 U.S. 15, 19 (1973).

[61] *See* note 24 *supra*.

[62] *See* text accompanying notes 121-216 *infra*.

It is true that television broadcasting traditionally has been regulated more closely than have other forms of speech, based on an argument of spectrum scarcity: because access to publicly owned airwaves is limited to licensees, the government has been allowed to oversee broadcast content to ensure that a variety of viewpoints is presented.[67] When regulating broadcasting, however, the Federal Communications Commission must tread a tightrope between its role as an overseer and its duty to respect the first amendment rights of broadcasters.[68] The FCC is prohibited by statute from interfering

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[63] Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 101-02 (1973); Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 386-90 (1969); United States v. Paramount Pictures, Inc., 334 U.S. 131, 166 (1948) (by implication).

[64] Red Lion Broadcasting Co. v. FCC, 395 U.S. at 390.

[65] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762, 770 (1976).

[66] *But see* Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582 (D.D.C. 1971), *aff'd mem. sub nom.* Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972). In *Capital Broadcasting*, the court held that the first amendment interests of broadcasters in airing commercial advertisements were not sufficient to override a congressional ban on cigarette advertising through the electronic media. The court suggested that broadcasters were merely "conduits" for advertisers' speech, that their interest in commercials was entirely economic and therefore did not give rise to substantial first amendment concerns. *Id.* at 584-85.

However, *Capital Broadcasting* was decided before the Supreme Court extended first amendment protection to commercial speech. *See* text accompanying notes 29-39 *supra*. Moreover, as Judge Skelly Wright argued in dissent, the *Capital Broadcasting* decision was seemingly inconsistent with earlier cases which had held that newspapers and film distributors could assert first amendment rights in protecting their media as forums for controversial speech. 333 F. Supp. at 591 n.25 (Wright, J., dissenting); *see* New York Times Co. v. Sullivan, 376 U.S. 254, 265-66 (1964) (newspapers); Joseph Burstyn, Inc. v. Wilson, 343 U.S. 495, 501-02 (1952) (film distributors).

[67] Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 388-89 (1969); National Broadcasting Co. v. United States, 319 U.S. 190, 226-27 (1943); *cf.* Miami Herald Publishing Co. v. Tornillo, 418 U.S. 241, 258 (1974) (holding that the "fairness doctrine," while applicable to the broadcasting media, could not be used to uphold a Florida right of reply statute since it unconstitutionally interfered with the publisher's editorial discretion). For a critique of spectrum scarcity as a basis for broadcast regulation, see Robinson, *The FCC and the First Amendment: Observations on 40 Years of Radio and Television Regulation*, 52 MINN. L. REV. 67, 156-59 (1967).

[68] *See* Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 102 (1973); Banzhaf v. FCC, 405 F.2d 1082, 1095 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969).

The delicate balance required in broadcast regulation derives from the dichotomous nature of the broadcast media: on the one hand, the airwaves are a public forum in which the interests with the right of free speech on the airwaves,[69] and, as federal licensees, broadcasters have primary discretion to decide what will be broadcast.[70]

Thus, while spectrum scarcity has been used to justify an affirmative obligation to present balanced programming, it does not justify an outright ban on forms of broadcast speech.[71] For example, in *Red Lion Broadcasting Co. v. FCC*,[72] the Court endorsed the FCC's "fairness doctrine," which requires that equal airtime be allocated to proponents of opposing views on certain public issues,[73] but cautioned that "the Commission's refusal to permit the broadcaster to carry a particular program . . . would raise more serious First Amendment issues."[74] More recently, the Supreme Court refused to find that the fairness doctrine required broadcasters to carry paid political advertisements.[75] The Court reasoned that to require editorial announcements would undercut the first amendment rights of broadcasters to determine programming content;[76] furthermore,

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of viewers and listeners must be paramount. Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 390 (1969). On the other hand, as the Supreme Court has noted, Congress in designing a system of broadcast regulation made a clear choice to place direct control over content in the hands of private licensees who, as speakers, cannot be stripped completely of their first amendment rights. Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. at 116. For a discussion of ways to reconcile the tensions between these two viewpoints, see Baker, *Free Speech and Federal Control: The U.S. Approach to Broadcasting Regulation*, 39 Mod. L. Rev. 147, 159-61 (1976); Comment, *The Regulation of Competing First Amendment Rights: A New Fairness Doctrine Balance After* CBS?, 122 U. Pa. L. Rev. 1283, 1293 (1974).

[69] 47 U.S.C. § 326 (1976) provides in pertinent part that "no regulation or condition shall be promulgated or fixed by the Commission which shall interfere with the right of free speech by means of radio communication."

[70] Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. at 116. The FCC has acknowledged that

> [t]he ascertainment of the needed elements of the broadcast matter to be provided by a particular licensee for the audience he is obligated to serve remains primarily the function of the licensee. His honest and prudent judgments will be accorded great weight by the Commission. Indeed, any other course would tend to substitute the judgment of the Commission for that of the licensee.

Network Programming Inquiry, Report and Statement of Policy, 25 Fed. Reg. 7291, 7295, 44 F.C.C. 2303, 2314 (1960) [hereinafter 1960 Programming Inquiry].

[71] *See* Children's Programming Inquiry, *supra* note 22, at 20-21.

[72] 395 U.S. 367 (1969).

[73] *Id.* at 375-86.

[74] *Id.* at 396.

[75] Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 121-25 (1973).

[76] *Id.* at 124. In a section not joined by the majority of the Court, Chief Justice Burger likened the role of broadcasters under the first amendment to that of trustees: their principal responsibility is to provide the public with balanced coverage of events and ideas, but they are given broad discretion to satisfy that responsibility as they see fit, subject only to general supervision by the federal government as licensor. *Id.* at 118-20 (Burger, C.J., announcing the judgment of the Court) (joined by Stewart & Rehnquist, JJ.).

those best able to finance editorial advertisement would monopolize and thereby undermine any fairness system.[77] Spectrum scarcity, then, has been seen as a logical basis for some intrusion on the rights of broadcasters—namely, the imposition of a general requirement of fairness. But the special characteristics of the broadcast media do not justify the complete abrogation of the free speech rights of broadcasters through a ban on children's advertising.[78]

In addition to broadcasters' first amendment interest in providing a forum for the exchange of commercial information, the FTC's proposed ban would have an impact on substantive programming decisions that poses serious constitutional problems. The acknowledged purpose in federal regulation of broadcasting is the protection of the public interest, not the maximization of corporate profits.[79] Nevertheless, the FCC also recognizes that "[a]dvertising is the basis for the commercial broadcasting system"[80] and, as such, it provides an economic incentive for quality "cultural" programming as well as the full variety of "commercial" broadcasting. The elimination of sponsorship might lead broadcasters to drop children's programming in favor of revenue producing programming.[81] The FCC recognized this possibility in 1974 when it rejected the proposal of Action for Children's Television (ACT) to ban advertising from children's programming; the Commission concluded that "[b]anning the sponsorship of programs designed for children could have a very damaging effect on the amount and quality of such programming."[82] The 1978 FTC Staff Report acknowledges this fear of the FCC, but it does not explore the possible ramifications of its own proposal.[83] To ensure the quality of children's programming without the economic incentive of advertising, ACT's 1970 petition had recommended regulations requiring broadcasters to devote time to children's programming.[84] Although the FCC refused to set such programming requirements, it noted that such "[r]ules would, in all probability, have been necessary had we decided to adopt ACT's proposal to ban advertising from children's programs."[85]

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[77] *Id.* at 123.

[78] It might be argued that the pervasive impact of television justifies regulation. *But cf.* Times Film Corp. v. City of Chicago, 365 U.S. 43, 77 (1961) (Warren, C.J., dissenting) (joined by Black, Douglas & Brennan, JJ.) (urging that potentially greater impact of motion pictures over other media on the viewing public does not justify greater regulation).

[79] Great Lakes Broadcasting Co., 3 F.R.C. Ann. Rep. 32, 32 (1929), *rev'd on other grounds*, 37 F.2d 993, *cert. dismissed*, 281 U.S. 706 (1930). 47 U.S.C. § 307(a) (1976) provides in pertinent part: "The Commission, if public convenience, interest, or necessity will be served thereby . . . shall grant to any applicant therefor a station license."

[80] Children's Television Report, *supra* note 3, at 39399, 50 F.C.C.2d at 11; *see id.* at 39399 n.11, 50 F.C.C.2d at 11 n.11; 1960 Programming Inquiry, *supra* note 70, at 7295, 44 F.C.C. at 2315 (recognizing the importance of advertising to public interest broadcasting, but finding no reason to distinguish noncommercial programs in evaluating station performance).

[81] Children's Television Report, *supra* note 3, at 39398-99, 50 F.C.C.2d at 8-11. Under the FTC staff's proposal, any program attracting an audience including a significant proportion of small children would be prohibited from carrying commercials. FTC Staff Report, *supra* note 9, at 10-11. Accordingly, in order to maximize profits, freely operating broadcasters would design programming in order to avoid attracting young audiences. Licensees admit that the removal of advertising from children's television would result in decreased spending on, and declining quality of, programs aimed at children. In a statement to the FCC, the American Broadcasting Co. wrote:

> A total ban or sharp curtailment of commercial advertising is self-defeating. The production of television programming is expensive. The removal or drastic reduction of advertising support would inevitably result in producers, directors, writers and talent withdrawing to devote their time and energies to more lucrative undertakings. Licensees in turn would be forced to select the least expensive program product for broadcast. The ultimate result would be an increase in low cost productions and a decrease in quality programming.

The issue of mandatory children's programming has not been raised expressly in the current FTC rulemaking, but must be considered in light of the serious first amendment concerns raised.[86] The FCC does have statutory authority to oversee " 'general program

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Comments of American Broadcasting Cos., Inc. at 12, Action for Children's Television, F.C.C. Docket No. 19142 (filed May 8, 1978).

[82] Children's Television Report, *supra* note 3, at 39399, 50 F.C.C.2d at 11.

[83] FTC Staff Report, *supra* note 9, at 338-41. The FTC staff deferred comment on this suggestion and announced its intention to elicit comment from the FCC in the course of rulemaking proceedings. The staff did recognize, however, that the FCC could not sanction deceptive or unfair advertising, whatever the economic effects on the broadcaster; and the staff noted that under the 1934 Communications Act, 47 U.S.C. § 309(a) (1970), as interpreted in the 1974 Children's Television Report, *supra* note 3, 50 F.C.C.2d 1, the broadcaster was *required* to provide programming for children as a condition of its broadcasting license. As a result, the broadcaster could not completely eliminate children's programming for lack of commercial support. FTC Staff Report, *supra*, at 338-41.

[84] Children's Television Report, *supra* note 3, at 39396, 50 F.C.C.2d at 1-2. ACT proposed a regulation which would require broadcasters to provide no less than 14 hours of children's programs per week, and would require age-specific programming during specified hours. *Id.*, 50 F.C.C.2d at 1-2. In requesting a mandated minimum number of hours for children's broadcasting, ACT's stated intention was to promote "*more* programs, more diversity, and a broader range of choice for the child audience." Reply Comments of Action for Children's Television at 20, Action for Children's Television, F.C.C. Docket No. 19142 (filed June 2, 1978). In response to ACT's petition, the FCC announced that it would carefully consider whether licensees were making a good faith effort to air material for children. Children's Television Report, *supra*, at 39397-98, 50 F.C.C.2d at 6-7.

[85] Children's Television Report, *supra* note 3, at 39397, 50 F.C.C.2d at 6.

[86] The courts have acknowledged that proposed rules must not intrude too deeply into the realm of licensee editorial judgment. *See, e.g.*, Action for Children's Television v. FCC, 564 F.2d 458, 480-81 (D.C. Cir. 1977); Straus Communications, Inc. v. FCC, 530 F.2d 1001, 1008, 1010-11 (D.C. Cir. 1976); Accuracy in Media, Inc. v. FCC, 521 F.2d 288, 296-97 (D.C. Cir. 1975), *cert. denied*, 425 U.S. 934 (1976).

format and the kinds of programs broadcast by licensees,' "[87] and has included children's programming among the "major elements usually necessary to meet the public interest, needs and desires of the community."[88] But to require a specified number of hours of noncommercial children's television would disrupt the uneasy balance between the agency's general affirmative duties and its recognition of the constitutional dangers inherent in government intervention in specific programming decisions.[89] The only means that could be employed to ensure some level of quality in children's broadcasting would be the establishment of the government as an arbiter of quality. The FCC would, in effect, become a member of each station's programming department, with ultimate responsibility for programming decisions. Such a policy would represent a far greater intrusion on the free speech rights of broadcasters than has ever been sanctioned by the courts.[90]

Thus, several first amendment concerns militate against a ban on advertising directed at children: the interest of society in legal and truthful advertising; the right of children to share in the first amendment freedoms of adults unless a compelling reason to restrict that right can be established; the right of advertisers to promote legal transactions truthfully; and the right of broadcasters to determine what advertising will be sent over the airwaves and to exert primary control over programming as part of a system which relies upon commercial revenues to motivate licensees.

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[87] Children's Television Report, *supra* note 3, at 39396, 50 F.C.C.2d at 3 (quoting Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 395 (1969)). Since its inception in 1929 as the Federal Radio Commission, the Commission has stressed that programming must be varied in order to properly serve the public interest. Great Lakes Broadcasting Co., 3 F.R.C. Ann. Rep. 32, 34 (1929), *rev'd on other grounds*, 37 F.2d 993, *cert. dismissed*, 281 U.S. 706 (1930). However, the FCC has added that its designation of program categories (*e.g.*, educational programming, political broadcasts, public affairs) is not intended to be a rigid schedule, but rather "the general character of programming to which licensees must conform in order to fulfill their public service responsibility." Children's Television Report, *supra*, at 39396-97, 50 F.C.C.2d at 4.

In dictum, the Supreme Court has endorsed the FCC's policy as consistent with its authority to grant licenses in the public interest. Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 393-95 (1969). The *Red Lion* majority wrote that the crucial interest in broadcast regulation is "the right of the public to receive suitable access to social, political, esthetic, moral and other ideas and experiences." *Id.* at 390. In Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94 (1973), the Court stressed that in recognition of broadcasters' first amendment rights FCC supervision should be limited to consideration of "whether a licensee's over all performance indicates a sustained good-faith effort to meet the public interest," *id.* at 127. *See generally* Note, *Regulation of Program Content by the FCC*, 77 HARV. L. REV. 701, 704-06, 714 (1964); Note, *The Listener's Right to Hear in Broadcasting*, 22 STAN. L. REV. 863, 868-81 (1970).

[88] 1960 Programming Inquiry, *supra* note 70, at 7295, 44 F.C.C. at 2314. The FCC has listed 13 other elements of programming necessary to serve the public interest: the opportunity for local self expression; the development and use of local talent; religious programs; educational programs; public affairs programs; editorialization by licensees; political broadcasts; agricultural programs; news programs; weather and market reports; sports programs; service to minority groups; and entertainment programming. *Id.*, 44 F.C.C. at 2314.

[89] *See* Banzhaf v. FCC, 405 F.2d 1082, 1095 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969); KIRO, Inc., 58 F.C.C.2d 86, 94-97 (1976).

[90] *See* Simmons, *Commercial Advertising and the Fairness Doctrine: The New F.C.C. Policy in Perspective*, 75 COLUM. L. REV. 1083, 1110 (1975) (making a similar argument against the application of the fairness doctrine to commercial advertisements.

The assertion of a presumptive right to broadcast children's advertising, however, by no means bars the FTC from regulating televised commercials directed at young audiences. If it can be shown that such advertising is deceptive, or that children are harmed by television commercials, then the balance might tip in favor of regulation. The presumption of constitutional protection should place a burden on the FTC to show that the proposed regulations are necessary to "cleanse" the airwaves.[91]

C. Time, Place, and Manner Restrictions

In a separate attempt to circumvent the first amendment protections accorded commercial speech by *Virginia Pharmacy*, the FTC Staff Report argued that the proposed ban should be characterized as a limited "time, place, and manner restriction."[92] Although the regulation challenged in *Virginia Pharmacy* did not itself fit within this classification, the Court did note that it frequently had allowed such restrictions to be placed on otherwise protected speech provided that they served significant governmental interests and were narrowly tailored to further those interests.[93] In a later case, Justice Powell expressed approval of such restrictions in the context of "pure" commercial speech, noting that "carefully tailored restrictions may be especially appropriate when advertising is accomplished by means of the electronic media."[94]

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[91] *See* Standard Oil Co of Cal. v. FTC, 577 F.2d 653, 662 (9th Cir. 1978); National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977), *cert denied*, 99 S. Ct 86 (1978); Warner-Lambert Co. v. FTC, 562 F.2d 749, 758-63 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978); Beneficial Corp. v. FTC, 542 F.2d 611, 618-19 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977); FTC v. Simeon Management Corp., 532 F.2d 708, 717 (9th Cir. 1976); Comment, *The Right to Receive*, *supra* note 44, at 802. *But see* Recent Development, *First Amendment Restrictions*, *supra* note 44, at 371-73 (arguing for broader FTC discretion).

[92] FTC Staff Report, *supra* note 9, at 290-95.

[93] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771; *see, e.g.*, Grayned v. City of Rockford, 408 U.S. 104, 116-17 (1972); United States v. O'Brien, 391 U.S. 367, 377 (1968).

[94] Carey v. Population Servs. Int'l, 431 U.S. 678, 712 n.6 (1977) (Powell, J., concurring in part). Other Justices apparently shared Justice Powell's view that such a restriction might be

The Court has cautioned that such restrictions will be allowed to outweigh first amendment protection "*provided* that they are justified without reference to the content of the regulated speech."[95] Furthermore, the degree to which time, place, and manner restrictions intrude on the protected speech must be evaluated: the Supreme Court has refused to permit the imposition of time, place, and manner restrictions which totally deny access to the marketplace.[96]

The FTC Staff Report does not detail the time and place restrictions to be imposed on broadcasters under the proposed rulemaking.[97] Presumably, however, effective regulation would ban commercials during the late afternoon and early evening hours, when more than half of the television programs watched by small children are broadcast. But large numbers of older children and adults are also present in the viewing audience during this period.[98] An effective

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permissible, even when based on content. Justice Stevens wrote: "In the area of commercial speech . . . the offensive character of the communication is a factor which may affect the time, place, or manner in which it may be expressed." *Id.* at 716-17 (Stevens, J., concurring in part).

[95] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771 (emphasis added). The impact of the Court's language requiring that time, place, and manner restrictions be content-neutral is by no means clear. The FTC argued that the Supreme Court has expressed a willingness to impose time, place, and manner restrictions that do take into account the content of the speech to be regulated. FTC Staff Report, *supra* note 9, at 290-95. In FCC v. Pacifica Foundation, 438 U.S. 726 (1978), the Court found that the content of certain speech justified its restriction to time periods when children would not be present in the audience. *Id.* at 749-51. Justice Stevens, speaking for a plurality of the Court, wrote broadly about classifications of speech based on content, concluding "it is undisputed that the content of Pacifica's broadcast was 'vulgar,' 'offensive,' and 'shocking.' " *Id.* at 747. Justice Stevens was careful to distinguish content-based regulation of indecent language, which he found permissible, from regulation based on the ideas or beliefs that might have been expressed, which he found impermissible. *Id.* at 744-48, *accord*, Young v. American Mini Theatres, Inc., 427 U.S. 50, 70-71 (1976) (plurality opinion); *see id.* at 86 (Stewart, J., dissenting) (indicating approval of content-based time, place, and manner restrictions in the limited context of a captive or juvenile audience).

In relying on these cases, however, the FTC staff failed to note that they involved sexually explicit materials, which, unlike other forms of speech, have traditionally been subject to regulation on the ground of offensiveness. *See* note 60 *supra*; text accompanying notes 187-95 *infra*.

[96] In Young v. American Mini Theaters, 427 U.S. 50 (1976), a sharply divided Court upheld a zoning ordinance restricting the location of "adult" movie theaters, but was careful to distinguish those cases in which a restriction on placement would totally deny access to the market to distributors or exhibitors of adult films. *Id.* at 62.

[97] Noting that children under eight are almost never a majority of the audience, FTC Staff Report, *supra* note 9, at 329, the staff recommended that the ban take effect "when younger children constitut[e] *more* than 'X' percent of the audience and adults constitut[e] *less* than 'Y' percent," *id.* at 330.

[98] Fifty-one percent of the television watched by children under the age of six is broadcast between 4:30 p.m. and 11 p.m., when 61% of the audience at large is also watching. The number of children under six in the viewing audience "peaks" at 8 p.m., when over 40% of the small children who watch television are in the viewing audience. NSF RESEARCH, *supra*

ban on advertising broadcast to small children thus would also affect programming broadcast to viewers who are capable of evaluating commercial messages. In effect, then, the proposed ban would reach beyond the scope of the proffered justification of preventing the undue influencing of young children. The impact of the second staff proposal—a ban on ads for highly sugared foods seen by older children—is even more striking: thirty-six percent of the programming watched by children between the ages of six and eleven is shown during the evening hours;[99] twelve of the fifteen television programs most popular among older children are shown during "prime time."[100] Twenty-five percent of the older children who watch television are still in the viewing audience as late as 10 p.m.[101] In order to be effective, then, the FTC's proposal would have to approach an almost complete ban on television advertising for sugared products, an impermissible intrusion on the advertiser's constitutional rights.[102]

It would be impossible, therefore, for the FTC to draft time restrictions that would eliminate advertising to younger children without also restricting the flow of commercial messages to the rest of the market. Similarly, sugared foods could rarely be advertised on television at all if they could not be directed at older children. Finally, the proposed ban on television advertising for highly sugared foods also appears to violate the proviso that time, place, and manner restrictions be content-neutral,[103] since it is based on the FTC's judgment

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note 20, at 14-15, 17. The A.C. Nielsen Co., whose statistics were used in the NSF report, subdivides the child audience into two groups—children aged 2-5 and children aged 6-11. *Id.* at 12. Accordingly, the data for "small children" do not include the entire target group that would be affected by the proposed ban (children under eight). This is especially significant in light of other NSF data which suggest that six- and seven-year-olds are more likely than younger children to watch "prime time" programs. *Id.* at 18.

[99] *Id.* at 15, 19 n.8.

[100] *Id.* at 19.

[101] *Id.* at 15, 17.

[102] In a situation analogous to the proposed ban, the Supreme Court held that Michigan's efforts to bar all sales of books "tending to the corruption of the morals of youth" violated due process because the regulation was not reasonably restricted to the "evil" the statute was designed to remedy. Butler v. Michigan, 352 U.S. 380, 381 (1957). The Court said that to purge the bookstores of material "not too rugged for grown men and women" in order to shield juveniles was "to burn the house to roast the pig." *Id.* at 383. It might thus be argued that reducing the amount and variety of commercials broadcast to largely adult audiences in order to protect the sensitivities of children similarly violates the Constitution. *Butler* may be distinguished, however: while a less restrictive means of regulation—simply barring the sale of such materials to minors—was available to the state in *Butler*, the FTC cannot restrict small children's access to television in the early evening hours. *See* FCC v. Pacifica Foundation, 438 U.S. 726, 748-51 (1978).

[103] *See* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771; text accompanying note 95 *supra*.

of the value of the product offered, and not the techniques employed in, or the placement of, the regulated advertisements.[104] In short, the FTC's proposal is not the "carefully tailored" restriction called for by Justice Powell,[105] but rather a blunderbuss which could broadly restrict all television advertising.

II

FTC AUTHORITY AND THE FIRST AMENDMENT

The *Virginia Pharmacy* decision[106] and the cases which have followed it[107] explicitly state that first amendment protection of commercial speech does not preclude regulation of false or misleading advertising. Such a conclusion is consistent with a balancing test approach to regulation: if false or misleading advertising has no first amendment value because the distribution of untruthful or confusing product information does nothing to promote informed decision-making, fair competition, or improved distribution of resources, then government regulations aimed at eliminating deceptive advertising should withstand a test which "assess[es] the First Amendment interest at stake and weigh[s] it against the public interest allegedly served by the regulation."[108] Some untruthful, noncommercial speech may be protected by the free speech and free press doctrines, because the exclusion of all false speech from first amendment coverage would have a chilling effect on speakers.[109] The Supreme Court has noted, however, that this consideration is not as compelling in the case of advertisers: since commercial speech is motivated by profits, there is less likelihood that regulations will chill truthful, protected advertising; and since advertisers, unlike other speakers, can more readily substantiate their claims, implementing the regulations imposes no unreasonable burden.[110]

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[104] *See* FTC Staff Report, *supra* note 9, at 122-56.

[105] Carey v. Population Servs. Int'l, 431 U.S. at 712 n.6 (Powell, J., concurring in part); *see* text accompanying note 94 *supra*.

[106] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 770-73.

[107] Bates v. State Bar of Ariz., 433 U.S. 350, 383 (1977); Standard Oil Co. of Cal. v. FTC, 577 F.2d 653, 662 (9th Cir. 1978); National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 162 (7th Cir. 1977), *cert. denied*, 99 S. Ct. 86 (1978).

[108] Bigelow v. Virginia, 421 U.S. 809, 826 (1975); *see* text accompanying notes 34-35 *supra*.

[109] "[E]rroneous statement is inevitable in free debate, and . . . must be protected if the freedoms of expression are to have the 'breathing space' that they 'need . . . to survive.' " New York Times Co. v. Sullivan, 376 U.S. 254, 271-72 (1964) (quoting NAACP v. Button, 371 U.S. 415, 433 (1963)). However, the Court has held that untruthful speech has no first amendment "value" in itself, even outside the commercial context. Gertz v. Robert Welch, Inc., 418 U.S. 323, 340 (1974).

What is unclear, however, is the breadth of the authority the regulators may draw from Supreme Court dicta. Because no Supreme Court commercial speech case since *Virginia Pharmacy* has involved federal regulation, the relationship between the FTC's statutory authority to regulate advertising and the dictates of the first amendment has not yet been established. Section 5 of the Federal Trade Commission Act empowers the FTC to define and limit "unfair or deceptive acts or practices in or affecting commerce."[111] Under this broad mandate,[112] the FTC has long exercised its power to proscribe untruthful and misleading advertising.[113] The FTC has been permitted to characterize advertising as misleading even absent any actual cases of deception; rather, the test is whether a given advertisement is likely to deceive.[114] Furthermore, it is not necessary for the FTC to find that the proscribed statement is likely to deceive a majority of consumers or even the average consumer. The Commission may prohibit an advertisement which would mislead "an appreciable or measurable segment of the public."[115] To the extent that the *Virginia Pharmacy* decision allows federal regulation of misleading or untruthful advertising, then, the currently recognized scope of FTC statutory authority would also seem to survive first amendment scrutiny.[116]

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[110] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771 n.24; *see* text accompanying notes 37-39 *supra*.

[111] 15 U.S.C. § 45(a)(1) (1976).

[112] Both the Congress and the courts have stressed that the powers granted to the FTC were intentionally nonspecific, in order to give the agency broad authority to ferret out and eliminate "unfair and deceptive" business practices in a manner that would not be possible under a clearer and more restrictive statute. S. REP. NO. 597, 63d Cong., 2d Sess. 33 (1914); H.R. CONF. REP. NO. 1142, 63d Cong., 2d Sess. 19 (1914); *see* FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 239-44 (1972); FTC v. R.F. Keppel & Bro., 291 U.S. 304, 310-14 (1934).

[113] *E.g.*, FTC v. Winsted Hosiery Co., 258 U.S. 483, 493-94 (1922); Consolidated Book Publishers, Inc. v. FTC, 53 F.2d 942, 945 (7th Cir. 1931), *cert. denied*, 286 U.S. 553 (1932); Miles Labs., Inc. v. FTC, 50 F. Supp. 434, 436-37 (D.D.C. 1943), *aff'd*, 140 F.2d 683 (D.C. Cir.), *cert. denied*, 322 U.S. 752 (1944).

[114] Charles of the Ritz Distrib. Corp. v. FTC, 143 F.2d 676, 679-80 (2d Cir. 1944). *See generally Developments in the Law—Deceptive Advertising*, 80 HARV. L. REV. 1005, 1040-43 (1967) [hereinafter *Developments—Deceptive Advertising*].

[115] Feil v. FTC, 285 F.2d 879, 892 n.19 (9th Cir. 1960); *see* Aronberg v. FTC, 132 F.2d 165, 167 (7th Cir. 1942) (FTC standards are designed to protect "the ignorant, the unthinking, and the credulous"); Benrus Watch Co., 64 F.T.C. 1018, 1045 (1964) (advertising held deceptive despite a poll that showed that only 14% of the audience was deceived), *aff'd*, 352 F.2d 313 (8th Cir. 1965), *cert. denied*, 384 U.S. 939 (1966).

[116] This is not to say that *Virginia Pharmacy* will have no impact on FTC regulation. Given the newly recognized constitutional protection of commercial advertising, the FTC will bear a

The FTC has also sought to proscribe advertising that is "unfair" although neither untruthful nor deceptive. For example, in 1964 the Commission issued its "Cigarette Rule,"[117] which proposed regulations that would require that cigarette packaging and advertisements carry warnings highlighting the hazards of smoking. The FTC justified its regulations by claiming that "a method of selling violates Section 5 if it is exploitative or inequitable and if, in addition to being morally objectionable, it is seriously detrimental to consumers or others."[118]

In 1972, the Supreme Court, in dictum, approved the FTC's criteria for proscribing as "unfair" advertisements that may not be deceptive.[119] However, the Supreme Court has never directly held that clear and truthful advertisements may be banned because of their alleged unfairness.[120] It is arguable that the unfairness standard

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heavier burden of proving that a disruption of commercial communication is justified. *See* text accompanying notes 150-54 *infra*. Moreover, the courts have held that the FTC restrictions must have the least possible impact on protected speech. *See* text accompanying note 44 *supra*. These limiting factors should result in increased freedom for advertisers. *See* Coase, *Advertising and Free Speech*, 6 J. LEGAL STUD. 1, 33 (1977). *But see* Note, *Yes, FTC, There is a Virginia: The Impact of* Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc. *on the Federal Trade Commission's Regulation of Misleading Advertising*, 57 B.U.L. REV. 833, 852 (1977) (arguing that "only advertising that a reasonable person could interpret as making a false assertion of material fact should be subject to regulation," and that the limiting dictum of *Virginia Pharmacy* suggesting that regulation of false or misleading advertising is permissible should be ignored).

[117] FTC Trade Regulation Rules, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, and Statements of Basis and Purpose of Trade Regulation Rule, 29 Fed. Reg. 8324, 8324-75 (1964) [hereinafter Cigarette Rule], *vacated*, 30 Fed. Reg. 9484 (1965). The FTC Trade Regulation Rule was obviated by congressional enactment of the Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340 (1976)). The Act affirmed the FTC's authority to regulate deceptive cigarette advertising, and the FTC still continues to use its "Statements of Basis and Purpose" as its principal authority for that regulation. *See* 30 Fed. Reg. at 9484-85.

[118] Cigarette Rule, *supra* note 117, at 8355.

[119] FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244 n.5 (1972); *see* Thain, *supra* note 4, at 659.

[120] The Elman Letter, *supra* note 46, suggests that although the Supreme Court has not specifically allowed a ban on truthful advertising due to unfairness, nevertheless it does not intend to limit the FTC's authority to stop "unfair" advertising. *Id.* at 2-3. Moreover, the Court will have to decide "what is the scope of 'unfair' within the context of the FTC Act and the constraints imposed by the [First] Amendment." *Id.* at 3.

In 1978, the Supreme Court did uphold a ban on direct solicitation by attorneys, despite the fact that such advertising was not necessarily deceptive or misleading. Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 464-68 (1978). However, the Court gave great weight to the argument that such solicitation poses a unique opportunity for deception because it cannot be supervised by bar officials. *Id.*

The Cigarette Rule was similarly based on considerations of "unfairness"; however, the Rule was drafted before the Court recognized that first amendment protection extends to commercial speech. *See* note 164 *infra*.

used by the FTC to justify its proposed rulemaking is overly broad in the context of first amendment protection, and therefore exceeds the constitutional limits of FTC authority.

A. *Deceptiveness*

1. *Small Children and Television Commercials*

Each of the FTC staff's proposed rules is supported by a separate argument concerning deceptiveness. The first rule, calling for the banning of all advertisements "directed to, or seen by, audiences composed of a significant proportion of children,"[121] seeks to prevent deception caused by the exploitation of those listeners too young to understand and evaluate commercial messages. Under this line of reasoning, if small children are incapable of understanding and evaluating advertisements, then such messages can hardly be said to contribute to informed decisionmaking.[122] In addition, since parents, and not children, are really the principal purchasers,[123] it is argued that advertising to children is really a means of selling to parents: advertisers bypass parents' intellectual defenses to the commercials themselves and substitute miniature screaming salesmen, parroting television commercials.[124]

The FTC staff recommendation was based on research findings summarized in the FTC's rejection of an earlier proposed ban on televised "premium" advertising for children:

> [T]he literature tends to support the conclusions that young children (1) fail to understand the nature and profit-making purpose of television commercials, (2) tend to trust and believe television advertising indiscriminately, (3) tend to recall only simple, concrete elements of commercials, (4) have difficulty distinguishing commercials from programs, and (5) tend to want whatever products are advertised on television.[125]

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[121] Children's Advertising Proposals, *supra* note 1, at 17969.

[122] FTC Staff Report, *supra* note 9, at 264-67.

[123] *See* NSF RESEARCH, *supra* note 20, at 138-43; Note, *Little Ears*, *supra* note 20, at 1151, text accompanying notes 194-95 *infra*.

[124] For example, the FTC Staff Report, *supra* note 9, argues that children's requests for given brands of cereals and snack foods are frequently granted by parents. *Id.* at 96-99. This contention is supported by studies discussed in the NSF RESEARCH, *supra* note 20, at v, 103-04. However, the NSF report also notes that no study of television advertising to children has yet determined its impact on the *overall* nutritional content of children's diets. *Id.* at v, 108.

[125] Premium Report, *supra* note 4, at 15070 (footnotes omitted); *see* NSF RESEARCH, *supra* note 20, at 25, 27-28, FTC Staff Report, *supra* note 9, at 82-91, 221-28

The FTC expressly cautioned, however, that the research results[126] did not justify the conclusion that advertised "premiums," let alone all advertising directed at children, were inherently deceptive.[127]

The FTC staff, in making its proposed regulations, relied on the FTC's authority to regulate deceptive advertising. This authority was recognized as early as 1934, when in *FTC v. R.F. Keppel & Brothers*[128] the Supreme Court approved the FTC's ban on an advertising technique that took advantage of children's naivete by offering inferior candy at inflated prices through the use of an enticing packaging device.[129] More recently, the FTC has used its regulatory powers to prohibit toy commercials which used sophisticated camera techniques to deceive children about a product's "lifelike" qualities,[130] and has ruled that certain Wonder Bread advertisements were false and misleading because they induced small children to believe that Wonder Bread produced extraordinary growth.[131]

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[126] Significantly, there is no consensus among researchers on the policy implications of their studies on advertising and children. Two University of Pennsylvania researchers argue that one's view as to the value of commercials depends on one's theory of child development. Robertson & Rossiter, *Children and Commercial Persuasion: An Attribution Theory Analysis*, J. CONSUMER RESEARCH, June 1974, at 13, 20. A learning theorist, who believes that children's understanding develops through experience, would consider commercials to be positive input enhancing children's understanding of their environment. On the other hand, one who believes that children move through fixed stages of development at a predetermined rate would conclude that small children are incapable of understanding commercials, and therefore withholding commercials will not retard their development as consumers. *See id. But see* Thain, *supra* note 4, at 679-82 (suggesting that even though further research may be necessary, the government should not wait before taking action).

Despite the uncertainty of the research results, exposure to commercials, and the resultant interaction between children and their parents, may teach children about the true nature of advertising and the commercial process. Insulating small children from television commercials merely delays "consumer socialization," the process by which children learn to become skeptical about advertising. This argument is bolstered by the FTC's recognition that older children tend to be more skeptical about television commercials than do younger children. FTC Staff Report, *supra* note 9, at 91-92.

As a result of these divergent views, the National Science Foundation has concluded that there is insufficient evidence to enable researchers to conclude what effects television, and the resultant parent-child interaction, have on the "consumer socialization" of children. NSF RESEARCH, *supra* note 20, at 127-31.

[127] Premium Report, *supra* note 4, at 15070. The Commission concluded that whatever the sensory impact of commercials on children might be, a ban was not justified since there was not sufficient evidence that television premium advertising induced the purchase of unsatisfactory products. *Id.* at 15072.

[128] 291 U.S. 304 (1934).

[129] *Id.* at 314. In its Cigarette Rule, *supra* note 117, the FTC claimed a longstanding special authority to promulgate regulations protecting children:

> Thus, throughout the law in general and under Section 5 of the Trade Commission Act in particular, it has been recognized that minors constitute an especially vulnerable and susceptible class requiring special protection from business practices that would not be unlawful if they only involved adults. Accordingly, a marketing practice, directed in a substantial part toward minors, that interferes substantially and unjustifiedly with their freedom of buying choice is an unfair or deceptive act or practice even if it is not especially pernicious as to adults.

Id. at 8358.

The FTC staff drew additional authority for the scope of its regulatory power from a provision of the Federal Communications Act which requires television and radio stations to clearly identify paid advertisements.[132] The FCC had explained that this statute was intended to prohibit practices that conflicted with the public interest responsibilities of licensees: "an advertiser would have an unfair advantage over listeners if they could not differentiate between the program and the commercial message, and were, therefore, unable to take its paid status into consideration in assessing the message."[133] If adults need protection from advertising which blurs the distinction between programming and commercials, the FTC staff argued, then children, who do not understand the distinction, should be protected from their own conceptual shortcomings.[134]

Citations to precedent and a superficial application of the Supreme Court's balancing test, however, merely mask the scope of the FTC's proposed action. Primarily, the situations in which FTC regulation was sustained all involved advertising techniques which concealed the purpose of commercial messages or the deficiencies of products.[135] Limitations on deceptive methods are wholly consistent with *Virginia Pharmacy*; by clarifying advertisements they foster communication of commercial information. The FTC's proposal, on the other hand, would not enhance communication, but rather eliminate it. Instead of regulating in the least intrusive manner, the FTC staff has, on the basis of minimal evidence, proposed the broadest possible intrusion on the distribution of commercial information to children.[136]

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[130] Topper Corp., 79 F.T.C. 681, 683 (1971); Mattel, Inc., 79 F.T.C. 667, 669 (1971).

[131] ITT Continental Baking Co., 83 F.T.C. 865, 961-62, *modified*, 83 F.T.C. 1105 (1973), *modified and enforced*, 532 F.2d 207 (2d Cir. 1976).

[132] FTC Staff Report, *supra* note 9, at 221-23 (construing 47 U.S.C. § 317(a)(1) (1976)).

[133] Children's Television Report, *supra* note 3, at 39401, 50 F.C.C.2d at 15, *quoted in* FTC Staff Report, *supra* note 9, at 221.

[134] FTC Staff Report, *supra* note 9, at 224-25.

[135] *See* text accompanying notes 124-33 *supra*.

[136] *See* text accompanying notes 155-65 *infra*.

2. *Implied Deception and the Hazards of Sugar*

The FTC's second proposed ban, on commercials for highly sugared foods directed at children aged eight to eleven, also represents an unconstitutional extension of the FTC's statutory authority to regulate deceptive commercial practices. The staff argued that children's advertising is deceptive if it does not reveal all of the adverse information about the product—a type of "implied deception."[137] Commercials for sugared foods are alleged to be deceptive not because they make positive statements claiming that eating sugar is healthful, but because they suggest that eating sugar is pleasant without mentioning its harmful side effects.[138] This proposition threatens all advertisers, however, because it is not limited to children's advertising:[139] the FTC's argument about sugared cereals could require all advertising to become a catalogue of consumer information, its selling purpose completely obscured.[140] Furthermore, the FTC's proposal

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[137] FTC Staff Report, *supra* note 9, at 164-65.

[138] The Staff Report asserts that the advertising is misleading because it portrays candy and sugared cereals as "desirable," *id.* at 164, and suggests that eating them is "the normal, pervasively accepted thing to do," "fully consistent with good health," *id.* at 165, without revealing that sugared products contribute to cavities and can lead to obesity. *Id.* at 166-67.

[139] Thain, *supra* note 4, at 668. In the case of cigarette advertising, for example, the FTC argued:

> [A]dvertising has associated cigarette smoking with such positive attributes as contentment, glamour, romance, youth, happiness, recreation, relaxation, comfort, and sophistication, at the same time suggesting that smoking is an activity at least consistent with physical health and well-being. . . .
>
> It is a deceptive act or practice for an advertiser to make representations concerning the satisfactions to be derived from using so hazardous a product as cigarettes without, at the same time, disclosing the dangers to health involved in its use.

Cigarette Rule, *supra* note 117, at 8356. However, the Cigarette Rule may be distinguished from the current rulemaking because of the greater harm to health resulting from cigarette smoking. *See* text accompanying notes 208-09 *infra*. In addition, the Cigarette Rule was based on considerations of "unfairness" rather than the relatively unsubstantial deceptiveness argument. *See* note 164 *infra*.

[140] A further extension could force those advertising large automobiles and gasoline to warn about air pollution, small car advertisers to discuss the added risks that light cars pose in accidents, aspirin advertisers to warn about stomach disorders, and coffee manufacturers to warn about nervousness and excess acidity. Thain, *supra* note 4, at 668-69. The rationale behind the FTC's analysis has already been pushed to an extreme by proposals that the psychological element of "image-based" advertising should be eliminated as either deceptive or unfair. One such proposal was to ban any advertising which displays products in proximity with:

> (1) a dramatic display of emotional pleasure; or (2) the satisfaction of emotional needs or desires; or (3) the alleviation of emotional anxieties or fears, where such pleasure, satisfaction, or alleviation is substantially unlikely to be similarly engendered by the actual product or use of the product or product type.

Reed & Coalson, *Eighteenth-Century Legal Doctrine Meets Twentieth-Century Marketing Techniques: F.T.C. Regulation of Emotionally Conditioning Advertising*, 11 GA. L. REV. 733, presents an expansion of currently recognized FTC authority. The courts have held that the FTC has only limited authority to find that advertisements are deceptive because of what they fail to say;[141] in general, findings of alleged deception are upheld only when the omission renders the advertising claims untruthful.[142]

In *National Commission on Egg Nutrition v. FTC*,[143] the Seventh Circuit upheld an FTC cease and desist order which barred an egg producers' trade group (NCEN) from incorrectly alleging in its advertisements that there is no scientific evidence linking eggs to heart disease.[144] The *NCEN* decision is consistent with the *Virginia Pharmacy* policy of careful line-drawing in regulation involving first amendment rights of advertisers.[145] Advertisements may be found deceptive—and therefore constitutionally and statutorily subject to FTC sanctions—when they misrepresent some objective and material fact; NCEN's advertisements could be regulated, therefore, to the extent that they "categorically and falsely denied the existence of evidence that in fact exist[ed]."[146]

The extension of first amendment protection to advertising under *Virginia Pharmacy* would be worthless if the FTC were free to proscribe advertising simply because the advertisement is effective and the FTC finds the product it offers less than perfect. If, as the Seventh Circuit held in *NCEN*, the first amendment limits the FTC's power to order balancing statements to those instances in which a balancing statement "is necessary to prevent [future] deception . . .

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775 (1977). Under this scheme the use of the slogan "Coke adds Life" would be illegal; and "the statement that 'Pet Milk makes you happy,' accompanied by the gleeful sounds of joyous children, probably would make that advertisement unfair since actual use of milk is 'substantially unlikely' to generate similar dramatic displays of emotion." *Id.* at 776. It is difficult to distinguish this extreme view from the position taken by the FTC staff. *See also* Note, *Psychological Advertising: A New Area of FTC Regulation*, 1972 WIS. L. REV. 1097.

[141] *E.g.*, FTC v. Simeon Management Corp., 532 F.2d 708, 715-16 (9th Cir. 1976) (weight reduction clinics not required to disclose that drugs utilized in treatment were not approved by the FDA); Alberty v. FTC, 182 F.2d 36, 39-40 (D.C. Cir. 1950) (advertisers not forced to discuss the limitations of an iron supplement).

[142] *See generally Developments–Deceptive Advertising*, *supra* note 114, at 1047-51.

[143] 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 99 S. Ct. 86 (1978).

[144] *Id.* at 164.

[145] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770-73 (1976); *see* text accompanying notes 29-39 *supra*.

[146] 570 F.2d at 163. The NCEN argued that its advertisements constituted the expression of the group's opinion on a controversial public issue. Such an opinion, it argued, had "higher" constitutional value than mere commercial speech and therefore was more resistant to regulation. *Id.* at 162-63. The court rejected this argument, finding that the advertisements were "made for the purpose of persuading the people who read them to buy eggs." *Id.* at 163.

or correct the effects of past deception,"[147] then it must be similarly unconstitutional to bar advertisers from merely representing their products in a favorable light.

3. *Overly Broad Regulation*

Although the extension of first amendment rights to commercial speakers does not protect deceptive advertising,[148] courts have held, after *Virginia Pharmacy*, that regulations of deceptive speech must be narrowly drafted and closely examined.[149] Prior to *Virginia Pharmacy*, the FTC had broad authority to reach conclusions about the effects of advertising and the propriety of remedies; and courts could upset FTC orders only if they were "unsupported by substantial evidence"[150] or "arbitrary, capricious, [or] an abuse of discretion."[151] The extension of constitutional protection to advertising has raised the standard of review, however, allowing the FTC to impose prior restraints on advertising only when they are "reasonably necessary to accomplish the remedial objective of preventing the violation."[152]

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[147] *Id.* at 164 (citations omitted).

[148] *See* text accompanying notes 106-07 *supra*.

[149] *E.g.*, Standard Oil Co. of Cal. v. FTC, 577 F.2d 653, 660-63 (9th Cir. 1978); Beneficial Corp. v. FTC, 542 F.2d 611, 618-20 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977).

It has been suggested that the overbreadth doctrine should not be used to strike down statutes regulating commercial speech. Bates v. State Bar of Ariz., 433 U.S. 350, 380-81 (1977); Comment, *Commercial Speech: Foreclosing on the Overbreadth Doctrine*, 30 FLA. L. REV. 479, 488-90 (1978). *But see* Bigelow v. Virginia, 421 U.S. 809, 815-18 (1975) (indicating that the statute struck down on other grounds might also have been subject to an overbreadth attack). The Supreme Court has reasoned that, "[s]ince advertising is the *sine qua non* of commercial profits, there is little likelihood of its being chilled by proper regulation and forgone entirely." Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771 n.24. The likelihood of such a "chilling effect" is the principal fear that justifies the use of the overbreadth doctrine. *See* Bates v. State Bar of Ariz., 433 U.S. at 380 ("[T]he justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context."). This does not mean, however, that the Court would refuse to strike down an overly broad statute which reached beyond acceptable goals to ban constitutionally protected speech. *See* Butler v. Michigan, 352 U.S. 380, 383-84 (1957) (statute prohibiting distribution of materials that would be offensive to children held to be overbroad because of its impact on the availability of such materials to adults).

[150] 5 U.S.C. § 706(2)(E) (1976).

[151] *Id.* § 706(2)(A).

[152] Beneficial Corp. v. FTC, 542 F.2d 611, 619 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977); *see* Warner-Lambert Co. v. FTC, 562 F.2d 749, 770-71 (D.C. Cir. 1977) (Supplemental Opinion on Petition for Rehearing), *cert. denied*, 435 U.S. 950 (1978); Comment, *The Right to Receive*, *supra* note 44, at 802 ("When a right to receive is established, the burden should shift to the government to justify the disruption of communication.").

Such a change in standards seems to be required under the balancing test for commercial speech. If regulation is permitted only when the governmental interest that compels correction

Thus, a restriction on advertising will be upheld only to the extent that it effectively cures deceptiveness.[153] Given the evidence that some methods of advertising to children are not deceptive, and that much of the deceptiveness deemed "inherent" in advertising directed at children may be eliminated by less restrictive means, it is apparent that the first amendment demands a case-by-case analysis of children's advertisements and does not permit sweeping regulation of an entire class of advertising.[154]

The FTC's first proposal assumes that all advertising directed at children aged eight to eleven is necessarily misleading, and that no regulation short of an outright ban can cure its deceptiveness. The National Science Foundation (NSF), however, suggests that certain techniques, such as separation devices which would clearly differentiate commercials from programming, the requirement of simplified language to communicate nutritional information, or the use of more effectively posed disclaimers, might cure much of the alleged deceptiveness of advertising directed at small children.[155]

Problems of overly broad application similarly plague the second proposal, a total ban on advertising of highly sugared products. As argued above,[156] "implied deception" is not a constitutionally acceptable basis of regulation. But even if the FTC's implied deception argument were to support some regulation of deceptive advertisements for sugared foods, it would hardly justify the broad ban suggested[157] by the FTC's second proposed regulation. This proposal fails to consider the deceptiveness of individual methods and advertisements and instead concludes that all advertising methods which are now

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outweighs the interests served by advertising, *see* text accompanying notes 34-36 *supra*, then regulation may be constitutional only to the extent that a harm requiring government intervention has been shown. This is in contrast to the treatment afforded obscene speech, which may be regulated without proof of harmful effects because "obscenity is not protected expression." Ginsberg v. New York, 390 U.S. 629, 641 (1968).

[153] Standard Oil Co. of Cal. v. FTC, 577 F.2d 653, 662 (9th Cir. 1978).

[154] In an earlier matter, the FTC indicated that it prefers case-by-case analysis of allegedly deceptive commercials to broad rulemaking for administrative reasons wholly separate from constitutional concerns. "There are distinct advantages in proceeding on a case-by-case basis where . . . the evidence [surrounding the controversy] is less than clear-cut. Particular commercials can present more concrete facts for the Commission's consideration. As a result, more specific guidelines may emerge." Premium Report, *supra* note 4, at 15072.

[155] NSF RESEARCH, *supra* note 20, at vii (Recommendation for Future Research). The NSF was critical of much of the research completed, citing researchers' failure to study "representative samples of commercials" to support the broad conclusions being derived from empirical research. *Id.* In short, "little is known about children's comprehension of product claims presented via techniques that are easily understood by adults." *Id.* at iii.

[156] *See* text accompanying notes 137-47 *supra*.

[157] *See* FTC Staff Report, *supra* note 9, at 331-33.

employed or might potentially be used to sell highly sugared foods are incurably deceptive.[158] The better remedy would be to promulgate regulations to correct each allegedly deceptive practice.[159]

The available research does not support the broad reach of the proposed regulation; on the contrary, the NSF has noted that "there is . . . preliminary evidence indicating that information about the nutritional content and value of food products can be effectively communicated to children . . . within commercials,"[160] and has recommended further research to discover the most effective means of teaching children about the nutritional consequences of their diets.[161] In proposing the broad ban, the FTC staff relied on an argument it had made to support its 1967 proposals for regulation of cigarette advertising;[162] as in the case of cigarette commercials, the staff argued, the cumulative effect of the barrage of sugared food advertising had been to establish "a barrier to adequate . . . knowledge and appreciation of the health hazards."[163] The FTC broadly regulated cigarette advertising as a class; but it did not ban cigarette advertising. Instead, it proposed health warnings to counteract the cumulative harm of industry advertisements.[164] The present proposal to ban television advertisements for highly sugared products goes far beyond this measured means of regulation.

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[158] *See id.* at 332. *But see* Premium Report, *supra* note 4, at 15072 (FTC resolved to proceed against advertising directed at children on a case-by-case basis).

[159] The FTC has frequently invoked, and the courts have approved, the remedy of affirmative disclosure to correct deceptive advertising. *E.g.*, Ward Labs., Inc. v. FTC, 276 F.2d 952 (2d Cir.) (advertiser required to disclose that baldness remedy was effective for only one relatively uncommon form of baldness), *cert. denied*, 364 U.S. 827 (1960); Firestone Tire & Rubber Co. v. FTC, 81 F.T.C. 398 (1972) (tire advertiser required to mention effect of various operating conditions on tire safety), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973); *see* Warner-Lambert Co. v. FTC, 562 F.2d 749, 759-61 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

[160] NSF RESEARCH, *supra* note 20, at 107; *see id.* at 104-05. Evidence in the FTC Staff Report itself also suggests that techniques employed by television commercials might be used to educate children. The report cites Joan Ganz Cooney, President of the Children's Television Workshop, who explained that her programs, *Sesame Street* and *The Electric Company*, were designed to resemble commercials in order to successfully educate children. FTC Staff Report, *supra* note 9, at 79 n.96.

[161] NSF RESEARCH, *supra* note 20, at 108. More strikingly, though, the proposed regulation seems to overlook the fact that parents and schools, not television commercials, should play the primary role in teaching children what and when to eat. Studies have suggested that if parents knew more about nutrition, they would supervise their children's eating habits more closely. *See* Clancey-Hepburn, Hickey & Nevill, *Children's Behavior Responses to TV Food Advertisements*, 6 J. NUTRITION EDUC. 93, 94-95 (1974) (research revealed that children of mothers who had knowledge of the validity of nutritional claims in snack food advertisements were less interested in the advertised foods); *see* NSF RESEARCH, *supra*, at 142.

[162] FTC Staff Report, *supra* note 9, at 173 (explaining Cigarette Rule, *supra* note 117, at 8357).

[163] *Id.* at 173-74.

Finally, the overbreadth of the FTC's ban on advertisement of sugared foods is revealed by its third proposal—the requirement of "nutritional and/or health disclosures" to balance advertisements for less-highly sugared foods.[165] If the less intrusive remedy of disclosure will cure the alleged deceptiveness of advertisements for products whose sugar content falls below some cut-off point, then the argument that no amount of disclosure could cure the alleged deceptiveness of commercials for products with slightly more sugar is difficult to accept.

B. *Unfairness*

In 1972, the Supreme Court cited with approval the "Cigarette Rule" criteria developed by the FTC to proscribe business and advertising practices which, although not "false and deceptive," were "unfair":

> "(1) whether the practice, without necessarily having been previously considered unlawful . . . is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen)."[166]

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[164] Cigarette Rule, *supra* note 117, at 8373-74. In the same context, a 1967 FCC order required that broadcast advertising for cigarettes be balanced by public service announcements about the hazards of smoking. Station WCBS-TV, New York, N.Y., 8 F.C.C.2d 381, *aff'd sub nom.* Applicability of the Fairness Doctrine to Cigarette Advertising, 32 Fed. Reg. 13161, 13173, 9 F.C.C.2d 921, 949-50 (1967), *aff'd sub nom.* Banzhaf v. FCC, 405 F.2d 1082 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969). In upholding the FCC rule, the Court of Appeals noted that a "balanced" discussion of the dangers of cancer promoted first amendment interests by fostering the "widest possible debate and dissemination of information on matters of public importance." Banzhaf v. FCC, 405 F.2d 1082, 1102-03 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969).

The FTC and FCC orders mandated public health advertising and warnings to balance advertisements for cigarettes. Following the ruling in *Banzhaf*, cigarette smoking declined nationally for the first time. Fearful of invoking antitrust liability, cigarette manufacturers could not unilaterally stop broadcasting cigarette commercials, and thereby eliminate the widespread "balancing" public health announcements. However, the industry's lobbyists did prevail upon Congress to ban cigarette advertising on radio and television, and thereby cut down on the effective antismoking advertising. *See* Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582, 587-90 (D.D.C. 1971) (Wright, J., dissenting), *aff'd mem. sub nom.* Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972).

[165] Children's Advertising Proposals, *supra* note 1, at 17969.

[166] FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244 n.5 (1972) (quoting Cigarette Rule, *supra* note 117, at 8355).

Neither the FTC nor the Supreme Court has determined whether all three of these factors must be present to support a finding of unfairness.[167] Both Congress[168] and the Court[169] have stressed, however, that unfairness is a flexible concept, and that the FTC may serve "like a court of equity" in weighing business practices against the public interest.[170]

However, the FTC staff may have exceeded this "equitable authority" by claiming that even if children's advertisements are not deemed to be deceptive, they should be banned under the FTC's authority to halt unfair business practices. As will be shown, advertisements directed at young children may not be proscribed constitutionally under either the unfairness criterion or the unscrupulousness criterion absent a showing of serious harm to consumers. Furthermore, the threat to health allegedly present in advertisements for sugared products is not great enough to justify the broad sanction proposed in the FTC Staff Report.

1. *Children's Commercials and Unfairness*

To justify its first proposal—to ban all commercials on programs seen by young audiences—the FTC staff asserted that, under the Cigarette Rule criteria,[171] television advertising directed at young children may be proscribed as unfair even if it is not deceptive. The staff argued that a marketing practice which enables adult advertisers to employ vast financial resources and clearly superior knowledge to exploit the gullibility and perceptual deficiencies of small children is "immoral, unethical, oppressive or unscrupulous,"[172] and therefore comes within the FTC's statutory power to regulate.[173] For authority, the staff relied on the common law doctrines of voidability of minor's contracts[174] and attractive nuisance,[175] which provide that children may not be lured into commercial transactions or potentially harmful situations.[176]

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[167] *See id.*; Thain, *supra* note 4, at 659 & n.48. The unfairness doctrine has been criticized for its "amorphous" nature. It has been argued that in its current state, the doctrine may be applied to a myriad of products, without a necessary balancing of consumer and advertiser interest. Schwartz, *Regulating Unfair Practices Under the FTC Act: The Need for a Legal Standard of Unfairness*, 11 AKRON L. REV. 1, 6-7, 19-20 (1977).

[168] H.R. REP. NO. 1142, 63d Cong., 2d Sess. 18-19 (1914); S. REP. NO. 597, 63d Cong., 2d Sess. 13 (1914).

[169] FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 239-44 (1972).

[170] *Id.* at 244; *see* FTC v. Brown Shoe Co., 384 U.S. 316, 320-21 (1966).

[171] Cigarette Rule, *supra* note 117, at 8355.

[172] *Id.*, *quoted in* FTC Staff Report, *supra* note 9, at 219.

[173] Federal Trade Commission Act § 5, 15 U.S.C. § 45 (1976); *see* FTC Staff Report, *supra* note 9, at 219-28.

[174] FTC Staff Report, *supra* note 9, at 210-11.

[175] *Id.* at 207-09.

In cases subsequent to the 1964 cigarette rulemaking, the FTC has indicated that under the proper circumstances, it might accept its staff's "unfairness" argument as a basis for stopping certain forms of advertising to children. For example, in *ITT Continental Baking Co.*[177] the FTC complaint suggested that Wonder Bread advertisements might be unfair because they led children to believe that Wonder Bread had extraordinary growth producing qualities.[178] The Commission declined to rule on the unfairness issue, however, striking down the advertisements on the alternate ground that they were false and misleading.[179] The FTC has never used unfairness alone as a ground for banning truthful advertising, and has given serious consideration to unfairness only when the third Cigarette Rule criterion—a threat of substantial injury to consumers—has been present.[180] For example, in a situation analogous to the current rulemaking, the FTC approved a consent agreement barring as unfair and deceptive the advertising of vitamins to children.[181] Significantly, the FTC's ruling on vitamin advertising was based in large part on the fear that such advertisements posed a serious health threat because they encouraged children, too young to understand the dangers of overdose, to take medications.[182] In the current rulemaking, however, the FTC staff has not claimed that all advertisements directed at small children pose an immediate or serious threat to their audience.[183] The FTC's unwillingness to rely solely on the first two elements of its three-pronged "unfairness" test, absent a showing of harm, is explicable in light of the first amendment concerns raised by *Virginia Pharmacy*: without harm to consumers or competitors, reliance on the two remaining criteria—whether the advertisements are within the penumbra of a common law doctrine or are unscrupulous—is equivalent to saying that advertisements may be banned if they are offensive.[184] And while a finding of offensiveness may seem

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[176] *See id.* at 206-18.

[177] 83 F.T.C. 865, *modified*, 83 F.T.C. 1105 (1973), *modified and enforced*, 532 F.2d 207 (2d Cir. 1976).

[178] *Id.* at 960-61.

[179] *Id.* at 963-64.

The use of unfairness as a basis for the protection of vulnerable groups such as children has been criticized as paternalistic. Moreover, "standards for what constitutes 'exploitation' of 'vulnerable' groups will be exceptionally elusive." Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 Harv. L. Rev. 661, 684 (1977).

[180] *See* Memorandum to Commission: Television Vitamin Advertising Addressed to Children, at 20 (filed Feb. 22, 1972); Thain, *supra* note 4, at 664 (noting that "the FTC has steadfastly refused to explore and implement the full scope of its authority to impose blanket prohibitions against certain kinds of advertising . . . under the 'unfairness' rubric"); Reed & Coalson, *supra* note 140, at 781-82 (1977) (acknowledging that the FTC has authority to regulate advertising that is unfair to consumers, but that it has focused instead on regulation of advertising that is deceptive).

[181] Hudson Pharmaceutical Corp., 89 F.T.C. 82, 86, 87-88 (1977).

[182] *See id.* at 86. In subsequent cases, the "unfairness" standard has been used as a basis for FTC action against advertising that threatened an immediate and substantial injury to children's health. *E.g.*, Uncle Ben's, Inc., 89 F.T.C. 131, 132-33 (1977) (advertisements depicting unsupervised children cooking rice discontinued); General Foods Corp., 86 F.T.C. 831, 838 (1975) (advertisements implying to children the safety of eating wild berries and plants banned); Philip Morris, Inc., 82 F.T.C. 16, 17 (1973) (distribution of sample razor blades in newspapers halted as posing immediate hazard, particularly to young children). The Cigarette Rule, from which

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the unfairness standards have been derived, also involved a known and substantial health hazard. *See* Cigarette Rule, *supra* note 117, at 8353-54; text accompanying note 209 *infra*.

A finding of substantial physical or economic injury to consumers has been the key element used by the staff to justify each of the FTC's proposed rulemakings based on the unfairness doctrine. *E.g.*, Staff Statement of Fact, Law and Policy in Support of the Proposed Rule and in Support of Affirmative Disclosure in Food Advertising, 39 Fed. Reg. 39852, 39858 (1974) (failure to disclose nutritional information is an unfair business practice because, "[w]hile nutritionally unwise food choices do not ordinarily pose an imminent danger to health, they quite clearly do affect health adversely if they are habitual"); Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 Fed. Reg. 23871, 23875-77 (1972) (failure to disclose octane ratings induced consumers to pay higher prices and to risk damage to their cars by buying higher octane gasoline than they needed); Trade Regulation Rule, Care Labeling of Textile Wearing Apparel, 36 Fed. Reg. 23883, 23889 (1972) (failure to disclose care information resulted in undue economic injury).

One commentator has suggested that the finding of a substantial injury to consumers should be a necessary element of any "unfairness" standard, for without such a requirement the doctrine would become too indefinite and expansive. *See* Schwartz, *supra* note 167, at 27-28.

[183] In dealing with the alleged "substantial injury" to children, the FTC Staff Report discussed only conclusions about the harmful aspects of eating sugared foods. FTC Staff Report, *supra* note 9, at 190-94. The staff further alleged that television damages the parent-child relationship by fostering conflict. *Id.* at 195-203. These alleged injuries, however, are not as serious as those threatened by the potential of vitamin overdose, by razor blades placed in Sunday newspapers or by poisonous roots—the instances in which the FTC has banned advertisements as endangering the health of children. *See* note 182 *supra*. Indeed, the NSF has noted that there is no evidence that directly links televised advertising of sugared products to deficiencies in children's nutritional health. NSF RESEARCH, *supra* note 20, at v. And the NSF has suggested that research may show that the interactions between parents and children induced by television commercials have a beneficial impact on child development. *Id.* at 130-31, 142, 143.

[184] The notion of unfairness absent deception or a proven economic or physical hazard is not unknown. In Pfizer, Inc., 81 F.T.C. 23 (1972), the Commission wrote that it was an unfair practice for an advertiser who made a claim for a product without having a "reasonable basis" for such claim. *Id.* at 62-64. Although the charge against Pfizer was dismissed because the evidence was inconclusive, *id.* at 73, the FTC nevertheless established the "reasonable basis doctrine" under which it now requires support for all product claims. *Id.* at 64. The issue is not whether the advertisement misrepresents the performance of the product, but whether the advertiser's actions are reasonable, and the evidence upon which such actions were based is adequate. Factors to be considered in evaluating reasonableness include (1) type and specificity of the claim made, (2) type of product advertised, (3) consequences of a false claim, (4) degree of reliance by consumers, and (5) type and accessibility of evidence. *Id.* For an early discussion of

to be an acceptable basis for proscribing speech under the FTC's current *statutory* authority,[185] the Supreme Court has established that offensiveness alone is not a constitutionally permissible basis for banning commercial speech.[186]

Some authority for banning "offensive" advertising directed at children might be drawn from the Supreme Court's recent decision in *FCC v. Pacifica Foundation*.[187] The Court held that offensive words may constitutionally be banned from the airwaves when it is likely that children are present in the audience.[188] The Court rejected Pacifica's argument[189] that the airwaves may not be censored absent a showing that the speech is obscene or harmful to children, deciding instead that "when the Commission finds that a pig has entered the parlor, the exercise of its regulatory power does not depend on proof that the pig is obscene."[190] Since broadcasters receive the least first amendment protection, especially when the speech being broadcast is offensive, the government may regulate such speech on the airwaves to protect the sensitivities of children.[191]

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the FTC advertisement substantiation program, see Note, *The FTC Ad Substantiation Program*, 61 GEO. L.J. 1427 (1973). The *Pfizer* doctrine has been criticized as unfair to advertisers because, under its expansive scope, they may be forced to conduct testing to substantiate truthful and harmless claims in instances in which the cost of testing may far surpass any benefit to society. Pitofsky, *supra* note 179, at 683; *see* Reich, *Consumer Protection and the First Amendment: A Dilemma for the FTC?*, 61 MINN. L. REV. 705, 728-29 (1977).

[185] Federal Trade Commission Act § 5, 15 U.S.C. § 45 (1976); *see* text accompanying notes 172-73 *supra*.

[186] Carey v. Population Servs. Int'l, 431 U.S. 678, 701 (1977); *cf.* Papish v. Board of Curators of Univ. of Mo., 410 U.S. 667, 670 (1973) (right to distribute campus newspaper); Healy v. James, 408 U.S. 169, 187-88 (1972) (right to have SDS chapter recognized as a campus organization); Cohen v. California, 403 U.S. 15, 20-21 (1971) (right to wear a jacket bearing an offensive protest against conscription).

[187] 438 U.S. 726 (1978).

[188] *Id.* at 749-50.

[189] Brief for Respondent at 50-53, 54-55, FCC v. Pacifica Foundation, 438 U.S. 726 (1978); *see* Brief of ACLU as Amicus Curiae at 38-43, FCC v. Pacifica Foundation, 438 U.S. 726 (1978).

[190] 438 U.S. at 750-51.

[191] *Id.* at 748-51. In support of the *Pacifica* ruling, both the majority and the concurring opinion cited Ginsberg v. New York, 390 U.S. 629 (1968), for the proposition that the state may control minors' access to indecent materials in order to assist parents who cannot always control what their children see and hear. 438 U.S. at 749-50; *id.* at 757 (Powell, J., concurring). The *Ginsberg* Court approved the use of a variable standard of obscenity, under which the states could ban the distribution to children of materials that "appeal to the prurient interest" of minors, even if such materials could not be barred from sale to the adult population. Ginsberg v. New York, 390 U.S. at 637-38. The *Pacifica* Court implicitly refused to accept the respondent's argument, Brief for Respondent at 50-53, FCC v. Pacifica Foundation, 438 U.S. 726 (1978), Brief of ACLU as Amicus Curiae at 41-42, FCC v. Pacifica Foundation, 438 U.S. 726 (1978), that the *Ginsberg* ruling protected children's rights to access to those materials that did not meet the obscenity test, including the offensive words broadcast by the Pacifica Foundation. *Compare* 438 U.S. at 749-50 *with id.* at 767 (Brennan, J., dissenting).

The broad language of *Pacifica* does not justify a ban on "offensive" advertising to children, however. In the case of pornography and indecent language, the claim of the regulators is that it is the content of the speech which is harmful to young audiences;[192] but, in the case of children's advertising, there is no proof that the speech itself is injurious to children.[193] Instead, it is asserted that unfair advertisements will induce children to demand and consume products that are not in the child's best interest.[194] But parents are stationed between their children and the alleged harm. The speech itself is not harmful, but merely communicates to children information that their parents are free to either act upon or ignore. In this situation, there is no justification for the government to step in.[195]

Some support for FTC authority to ban truthful advertisements under its "unfairness" power may be found in *Ohralik v. Ohio State Bar Association*,[196] a recent Supreme Court decision upholding a state ban on in-person solicitation by attorneys.[197] In *Ohralik*, the Court recognized that such solicitation may be an effective means of distributing information about available legal services,[198] but nevertheless concluded that the method was especially susceptible to abuse. The likelihood that attorneys would use such solicitation to mislead their prospective clients, and the possible serious ramifications of these actions, justified banning the method itself.[199]

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[192] *See* FCC v. Pacifica Foundation, 438 U.S. at 748-50; Ginsberg v. New York, 390 U.S. at 640-43.

[193] Most researchers and observers have stressed the incomplete nature of the research on television advertising and children. In general, research has not discovered the "long-range consequences of growing up with TV commercials . . . . Even the short-run effects demonstrated are modest." Span, *Scrunchy-Munchy Sugar-Poo*, Boston Herald American, Oct. 22, 1978, Magazine, at 9, col. 1, 10, col. 4. The NSF research concluded that while advertising undoubtedly plays a role in the development of children's consumer behavior, nothing has been proven about the effects of television commercials on children, either in terms of children's susceptibility to advertising or their development as consumers. NSF RESEARCH, *supra* note 20, at v-vi, 127-33, 149. And although the FTC staff has argued that television advertising works a substantial injury to the parent-child relationship, FTC Staff Report, *supra* note 9, at 195-203, the NSF concluded that "[d]isappointment, conflict, and anger are reported when parents deny children's purchase requests. Further research is needed to examine the persistence of these effects, and also to gauge the extent to which parents utilize these occurrences for consumer instruction purposes." NSF RESEARCH, *supra* note 20, at vi-vii; *see id.* at 148-49; Premium Report, *supra* note 4, at 15070; Note, *Little Ears*, *supra* note 20, at 1150-54.

[194] FTC Staff Report, *supra* note 9, at 190-93.

[195] The FTC staff suggested that one objective of its rulemaking is to relieve parents from the discomfort of denying their children's requests for advertised products. *Id.* at 202-03. At least one critic of this position has questioned whether the FTC is acting within its authority when it attempts to mediate between parents and children: "Will the assumption of the Commission be that parents are incompetent to intermediate in these decisions for their children? If so, is it the Commission that is to become the superparent and decide what the child can and cannot see and ask for?" Comments of Gil Weil Before Children and Advertising Seminar Series, Georgetown University Law Center, Summary of Jan. 23, 1978 Session, at 5 (copy on file at *New York University Law Review*).

[196] 436 U.S. 447 (1978).

[197] *Id.* at 468.

[198] *Id.* at 457-58.

Advertising directed at young children is, to some extent, similar to the solicitation in *Ohralik*: like the attorney who uses his superior knowledge and persuasive powers to browbeat an accident victim who may not be in full control of his powers of reason, the advertiser enters the home through an electronic device to entice children whose reasoning powers may also be limited.[200] The case against children's advertising is not sufficiently like the case against Albert Ohralik, however, to justify a broad ban. Children under the age of eight are not the decisionmakers; it is their parents who decide what will and will not be bought.

2. *The Advertisement of Sugared Products*

Unlike its first proposal, the FTC's second proposal, to ban all advertising of sugared foods seen by children,[201] did allege actual and substantial harm to consumers. Since sugared food consumption "poses the most serious dental health risks,"[202] the FTC staff claimed that a ban on advertising of these products would be justified under the third Cigarette Rule criterion.[203] Much of the Staff Report focuses on medical evidence that the consumption of sugared products promotes tooth decay and, when it reaches the point of excess, obesity and diabetes.[204] But several problems are raised by this argument. Certainly the government has the power to regulate the sale and distribution of products that pose a health threat. It is unclear, however, how great a threat and how serious an injury must be present to justify a ban on speech.

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[199] *Id.* at 460-62. In a more recent case, the Court upheld a ban on optometrists' use of trade names, a form of commercial speech, because of the significant possibility that such a practice would be used to deceive customers about the quality of services. Friedman v. Rogers, 99 S. Ct. 887, 895-96 (1979).

[200] The FTC staff suggests that the alleged unfairness of advertising directed to children may be exacerbated by the use of television—an electronic medium especially suited to hold the attention of young audiences. FTC Staff Report, *supra* note 9, at 83-85; *see* R. SHAYON, TELEVISION AND OUR CHILDREN 33-39 (1951).

[201] FTC Staff Report, *supra* note 9, at 11.

[202] *Id.*

[203] *Id.* at 190-94; *see* text accompanying note 166 *supra*. It is arguable that even if the alleged dangers of sugar consumption present a sufficient basis for *someone* to regulate the advertising of sugared products, they do not justify FTC regulation. The FTC has no apparent authority to regulate either the consumption of sugar or the amount of sugar that may be allowed in food products. The authority to regulate adulterated or misbranded food is vested in the Food and Drug Administration. 21 U.S.C. §§ 331, 333, 334, 342 (1976); *see* text accompanying note 212 *infra*. And Congress, in its discretion, may set a national policy regarding sugar consumption. Accordingly, the FTC's effort to turn its own judgment about sugared foods into a national policy against sugar consumption seems to exceed its statutory authority, first amendment concerns aside. *Cf.* Bigelow v. Virginia, 421 U.S. 809, 822-29 (1975) (holding that Virginia's ban on advertising for legal abortions was beyond the scope of the state's direct authority to influence the behavior of its citizens, and was therefore entitled to little weight in a constitutional balancing test).

The FTC staff found considerable support[205] in Congress' 1969 ban of broadcast advertising for cigarettes,[206] upheld in *Capital Broadcasting Co. v. Mitchell*.[207] However, even if a congressional ban on broadcast advertising for cigarettes was warranted,[208] it does not follow that the FTC may similarly ban commercials for sugared products. As the FTC itself argued when it passed the Cigarette Rule, the ban on cigarette advertising does not justify similar action against sugar, because the long-term harmful effects of sugar consumption result only from abusive overeating, while cigarettes are habit-forming drugs which pose an intolerable threat to health even when used in moderation.[209] Thus, it is clear, in the context of the constitutional balancing test, that the threat posed by cigarettes justifies a higher degree of interference with protected rights than do the alleged dangers of sugar consumption. The state interest in protecting the public from treatable dental cavities is hardly as compelling as the need to control cancer.

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[204] FTC Staff Report, *supra* note 9, at 105-56.

[205] *Id.* at 268-71.

[206] Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 2, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. § 1335 (1976)).

[207] 333 F. Supp. 582 (D.D.C. 1971), *aff'd mem. sub nom.* Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972).

[208] *Id.* at 584.

[209] Cigarette Rule, *supra* note 117, at 8361-62. To dispute the assertion that the Cigarette Rule might be unduly expanded to require affirmative disclosures in advertising for a myriad of consumer products, the FTC argued that the documented evidence clearly linking smoking to heart disease and cancer differentiated cigarettes from other consumer products, including sugared foods, for purposes of the unfairness doctrine. *Id.* at 8361-63. The FTC did note that "[s]hould it some day become established that consumption of any of these foods [including sugared products] is as dangerous as cigarette smoking, remedial action by the Trade Commission, the Department of Agriculture, or some other agency might be appropriate." *Id.* at 8362. The FTC staff now argues that changing scientific views about sugar and its long term impact on health vitiate the differentiation the Commission made in the Cigarette Rule. FTC Staff Report, *supra* note 9, at 174-75. However, the Department of Agriculture (USDA), which is responsible for "safeguard[ing] the health and well-being of the Nation's children" in federally funded food programs, 42 U.S.C. § 1771 (1976), does not agree with the FTC that the case against sugar is so clear-cut. The USDA declined to ban sugared cereals from distribution in its "Special Supplemental Food Program for Women, Infants and Children," pending additional investigation, concluding that "there is some disagreement in the scientific literature regarding the correlation between various sugars and health problems." 42 Fed. Reg. 43205, 43212 (1977).

The availability of other, less intrusive means of controlling sugar consumption also dictates against the constitutionality of the proposed ban. In *Virginia Pharmacy*, the Court recognized the legitimacy of the state's interest in holding pharmacists to high professional standards,[210] but nevertheless concluded that a ban on advertising was not an acceptable means to effect that interest: "Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways. . . . But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering."[211] In the present situation, the government may also have other less restrictive options if it elects to conduct a war against sugar. One critic has suggested that sugar could be removed from the Food and Drug Administration's list of foods "Generally Recognized as Safe,"[212] and that Congress could stop "subsidizing" sugar production, stop funding any school breakfast or lunch program that serves highly sugared cereals, take candy out of school lunchroom vending machines, make highly sugared products ineligible for food stamp purchases, and, most directly, simply limit the sugar content of breakfast cereals and snack foods.[213]

The FTC Staff Report argued that the mandate of *Virginia Pharmacy* to use means of control other than complete suppression of commercial speech should not be applied to the proposed rulemaking on sugar because sugared product advertising is directed at children, whose reasoning powers are limited and who therefore have no interest recognized by the commercial speech doctrine.[214] But the FTC cannot rationally distinguish *Virginia Pharmacy* on the basis of the difference between adult and child audiences: the ban on advertising for highly sugared products is not focused on commercials directed at very young children, whose conceptual and perceptual difficulties were discussed above,[215] but on those directed at older children, who, according to the FTC staff's own report, do understand the selling purpose of commercials and are more likely to be skeptical of advertised messages.[216]

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[210] 425 U.S. at 766-70.

[211] *Id.* at 770 (citation omitted); *cf.* Linmark Assocs., Inc. v. Township of Willingboro, 431 U.S. 85, 94-97 (1977) (noting that while the state interest in promoting racially integrated housing is legitimate and important, restricting the free flow of information by prohibiting the posting of "for sale" signs is an unconstitutional means to achieve that objective).

[212] *See* 21 C.F.R. § 182.1(a) (1978).

[213] Comments of Richard Jencks Before the Children and Advertising Seminar Series, Georgetown University Law Center, Summary of Feb. 27, 1978 Session, at 4-5 (copy on file at *New York University Law Review*). Mr. Jencks, a broadcast consultant, is former president of the CBS Broadcast Group.

[214] FTC Staff Report, *supra* note 9, at 258-60.

What emerges, then, is a difficult balance. On one side is the FTC's duty to protect consumers from unfair business practices or physical harm; but against this duty must be weighed the first amendment rights of advertisers to disseminate commercial information. To the extent that the ill effects of unfair practices are shown, the Commission should be free to regulate unfairly manipulative advertising practices, and perhaps ban them altogether, when the potential hazards are so great and so likely to occur that an individualized consideration of particular commercials would be ineffective. That case, however, has not been made against children's advertising. The FTC's assertion that all advertisements directed at small children are unfair or unhealthful is certainly contrary to the policy of careful line-drawing required by the constitutional doctrine which prohibits the silencing of protected speech merely because it offends the sensibilities of some members of society.

CONCLUSION

Unpopular speech frequently poses difficult first amendment questions, and children's advertising is no exception. Each side of the debate is charged with emotional issues that make any constitutional balance difficult to strike. The FTC's popular crusade against children's advertising is filled with assertions that would expand the Commission's power to promulgate content-based regulations of advertising. In an effort to protect children, the Commission has drafted a report which, if accepted, would enable it to broadly interfere with commercial speech on several fronts in an unprecedented manner. Such an expansion, in the form of a broad assault on an entire class of speech, cannot be upheld if the constitutional protection recently extended to commercial speech is to remain meaningful.

This does not mean that the FTC is powerless to regulate advertising directed at young audiences. The FTC has longstanding authority to control advertising techniques that prey on and mislead the public by deceptive assertions and omissions. The commercial speech cases make it clear, however, that the role of regulators is to preserve communication in the marketplace, and to ensure that advertisements are clear and truthful. Any regulations premised on the assumption that the proper detergent for cleansing the flow of commercial speech is silence violate both the letter and the underlying policy of the commercial speech doctrine.

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[215] *See* text accompanying notes 121-25 *supra*.

[216] FTC Staff Report, *supra* note 11, at 78-91 (indicating that children's ability to differentiate between programming and commercials, and to understand the selling purpose of advertising, increases with age); *see* NSF RESEARCH, *supra* note 20, at 27-32.

The Current Status Of Comparative Advertising

STEPHEN W. BROWN
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Advertisers warn us not to confuse the Ford Granada with a Mercedes-Benz and they ask us to compare the shave of the Remington razor with that of any razor blade. These are examples of comparative advertising — the practice of naming a competing product in an advertisement and making a direct comparison.

Comparative advertising has touched off considerable controversy in the advertising industry. Some leaders vigorously support the practice while others condemn it. Victor Bloede, Chairman of Benton and Bowles, says "There is nothing wrong with naming names. It is neither illegal nor immoral. And it isn't even fattening."[1] Tracy Western, Director of the FTC Bureau of Consumer Protection, commented on the charge that comparison advertising is confusing. He feels "confusion is a higher state of knowledge than ignorance."[2] Stanley I. Tannenbaum, Chairman of Kenyon and Eckhardt, views comparative advertising as "advertising's own brand of consumerism."

Advertising that compares one or more brands of a product has increased in the last few years with the encouragement of the Federal Trade Commission. This article explores the background, nature, and frequency of comparative advertising and discusses strategies and effectiveness of such advertising.

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Strong opposition to these favorable opinions has also developed, however. One of the most outspoken critics is Andrew G. Kershaw, Chairman of the Board of Ogilvy and Mather. He views the comparisons as extremely damaging to advertising's credibility and possibly destructive to the free enterprise system due to the loss of respect for business.[4] Jack Roberts, also of Ogilvy and Mather, warns that comparative advertising may turn business into a "carnival brand name shooting gallery."[5]

Although many firms have always used comparative messages in their personal selling efforts, the practice of using comparative messages in advertising is relatively new. The purpose of this article is to explore the area of comparative advertising with special attention to the regulatory environment, the use of this form of advertising, the strategies used to compare products, and the effectiveness of the technique.

ENABLING CONDITIONS

Brand "X"

Comparative advertising has been used for many years. In the early 1930s, for example, Plymouth challenged the consumer to compare their car with the "big 3." However, prior to the 1970s, many advertisers shied away from comparative advertising despite the absence of any regulations against it. Perhaps this was due to an unwritten code of honor within the advertis-

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ing industry. Much comparative advertising was limited to those comparisons between "Brand X" or an obliterated "bleep" brand and the identified sponsor. The consumer almost never knew if the unnamed brand was real or fictitious. Sometimes, however, Brand X was presented so that an average viewer could easily identify it, for example when Bell and Howell compared their photocopier to Brand X, most people knew Brand X was Xerox. Another example is the no-name battle between SOS and Brillo scouring pads. Each referred to its rival only as "that pink pad" or "that blue pad." The product brand names were never mentioned.

Naming Names

In 1971, the Federal Trade Commission (FTC) began taking steps to encourage comparative advertising, hoping to provide more tangible product information to consumers and also to open up a new range of creative marketing strategies. The FTC staff suggested that consumers might be able to make better product choices by knowing the identity of the competing brands, and they began to campaign actively for the legitimization of comparison advertisements on all networks in late 1971. Robert Pitofsky, Director of Consumer Protection, led the campaign by writing a series of letters explaining the situation and asking that CBS and ABC accept comparative advertisements on their networks. NBC already allowed comparative advertisements but few were shown. This was because of the high cost to advertisers of making a comparative advertisement for NBC and another noncomparative advertisement for CBS and ABC. The FTC reasoned that by allowing comparisons, advertising would become similar to *Consumer Report* in the offering of comparative product information.

There were also rumors that refusal to run comparative advertisements might be considered restraint of trade. If firms were not allowed to brag freely about their "better mousetrap" there would be less competition and less inclination to introduce new products. Finally, because the use of Brand X and beeped comparisons left open so many opportunities to mislead the consumer, the FTC hoped real comparisons would discourage this sort of deception. In short, they hoped to open up a new era of corporate accountability resulting from comparative advertising programs.

This encouragement for comparisons was not without its critics, however. The American Association of Advertising Agencies (AAAA) has attempted to keep advertising standards high in order to build credibility for advertising. Their 1962 revised *Standards of Practice* recognized that "keen and vigorous competition, honestly conducted is necessary to the growth of American business" and that advertising is part of this. It also mentions the potential of weakened public confidence should unfair competitive practices begin. *The Creative Code*, which is endorsed by the AAAA and several other organizations and industries, includes a statement against "comparisons which unfairly disparage a competitive product or service."* Until recently, CBS and ABC felt that just naming names constituted disparagement.

The AAAA was deeply concerned with comparative advertising and have had numerous committees study the subject. Policy statements were published in 1966, 1967, 1969, and all of them tended to discourage comparison advertising. It was not until 1974 that their position changed.

Statement of Policy

The AAAA issued a "*Policy Statement and Guidelines for Comparative Advertising*" in April, 1974. Basically, the provisions required that: (1) The advertisement should inform and not discredit others. (2) The advertisement should name only significant competition but not in a degrading or unfair manner. (3) Similar product properties should be the only ones compared, not trivial differences. (4) If a test is made, it should be objective, preferably done by an independent testing facility. (5) All claims must be supported, and full results must be reported so as not to lead consumers to improper conclusions based on partial and biased results.

In addition to the AAAA Policy Statement, a *Television Code* was developed that has allowed comparative advertising since January 1974, as long as the comparisons are fair. A *Radio Code* has also been developed, which asks that comparisons be "confined to specific facts rather than generalized statements or conclusions." NBC has written its own set of *Comparative Advertising Guidelines* that are very similar to the AAAA Policy Statement. The print media has no current regulations in this area.

Regulations

Regulating comparative advertising is still very difficult despite these recent advances. Before a commercial can be shown on any network, it must be reviewed by that network's own clearance staff for taste and accuracy. Because of the tremendous load (up to 50,000 commercials per year) and highly technical test results, the job is extremely difficult. Compounding the difficulty is the tendency for advertisers to design tests that weigh the results in their product's favor.

Self-regulatory bodies move into action if an advertisement is ever questioned. The National Advertising Division of the Council of the Better Business Bureau examines the test data used to substantiate the advertiser's claim. This division then makes a decision. If the decision is appealed, it goes to the National Advertising Review Board for their decision. The truth is often difficult to uncover and, even when it is, no channels are readily available for retribution.

NATURE AND FREQUENCY

Estimates suggest that comparative advertising constitutes from 7 percent to 25 percent of total advertising. This wide range is due in part to the different definitions of comparative advertising. Wilkie and Ferris offer the following:[9] (1) compares two or more specifically named or recognizably presented brands of the same generic product or service class; (2) makes such a comparison in terms of one or more specific product attributes.

Different levels of intensity are also possible, ranging from "a very casual mention of a competitive brand to a very high level point-by-point comparison of the sponsored and competing brands."[10] A low level comparison may only refer to the competition as "the leading brand." An example of a high level comparison advertisement would be American Motors' point-by-point comparison between their Gremlin and the competing Pinto and Vega.

In a prior study, however, the authors of this article made a distinction between strictly comparative and implied comparative advertising.[11] Strictly comparative advertisements encompass situations where competition was named and/or shown. Implied comparisons, on the other hand, are those that compare the sponsor to "Brand X", to other brands in general, or even to other products produced by the same company. An example of this last type is a recent deodorant advertisement where a woman says "I'm throwing out my old Secret for something better. New Secret!"

Television Advertising

When the broad definition was used, the study found that 19 percent of observed television advertisements could be classified as comparative in nature. That percentage goes down to 3.6 percent, however, when only strictly comparative advertisements are counted. These account for only about 3 percent of total advertising time. Thus, the controversy about comparison advertising is confined to a relatively small amount of advertising.

The researchers were also interested in whether any products were more often associated with comparative advertisements. They found that nonprescription drugs were the most commonly compared items. Some of the products include aspirin, cold tablets, allergy pills, and sleeping aids. Several other products found to be moderately associated with comparison advertisements were "household products, food, consumer durables, and personal care products."

Another question investigated by the study was the nature of the comparisons. It was found that 80 percent of the time, quality was compared, price was compared only 12 percent of the time. It was suggested that this may be due to the fact that price is more difficult to control and is subject to local fluctuations and thus may not be suitable for national media."[12]

Magazine Advertising

Comparison advertising in magazine articles was observed in another study by Jackson, Brown, and Harmon. The basic questions asked were again in regard to nature and frequency.[13] Comparison advertising was also investigated in conjunction with the type of magazine in which it was found.

Four different types of magazines were used in the areas of general editorial *(Reader's Digest)*, men's *(Esquire)*, women's *(Ladies Home Journal)* and business *(Newsweek)*. A range of fifteen years was covered by observing magazines in 1960, 1965, 1970 and 1975. Definitions used in the study were very similar to the ones used in Brown and Jackson's study of television comparison advertising.

The frequency of comparative messages represents only 8 percent of the advertisements using the broad definition. If the strictly comparative meaning is used, the percentage falls to 1.2 percent. When these results are related to the frequency of comparative television advertisements, the low percentages are not too surprising. Over time, the frequency has increased moderately. In 1960 the number of total comparative advertisements was 6.[illegible] percent; by 1975 it had increased to 9.8 percent. The implied category stayed fairly level over the years at approximately 7 percent, while strictly comparative advertisements increased from 0.1 percent in 1960 to approximately 3 percent in 1975.

Significant differences were found among the magazines. *Readers Digest* had the highest percentage of comparisons (12.9 percent) followed by ***Ladies Home Journal*** at 7 percent, ***Newsweek*** at 6 percent, and ***Esquire*** at 4 percent. Perhaps these differences are related to the finding that drugs and household products, which are more likely to be comparatively advertised, are more prevalent in a source such as ***Readers Digest***. Analysis of the number of products compared in each advertisement showed that approximately 50 percent compared one or two other brands with the sponsor, while 29 percent compared the sponsor to five or more brands. The latter type is usually a comparison to the "leading brands" without a specific indication of names.

In summary, examination of television and magazine advertisements indicates that strictly comparative advertisements are a relatively small part of all comparative advertisements, which in turn are a small part of total advertising. Comparative advertising is increasing, however, and certain product areas are more likely to be comparatively advertised.

STRATEGIES

Even with so few comparative advertisements relative to total advertising, definite comparative advertising forms and strategies have begun to take shape.

Considerations

The Brands Themselves. To begin with, the number of brands to be mentioned and the brands themselves play an important part in the advertisement. Should contrasts be intense or subtle? Contrasts between very minor product attributes may be perceived as meaningless or deceptive. Also, if the sponsor's brand wins in every test, the advertisement may not be as believable as an advertisement in which the product loses part of the time. Opel ran an entire advertising campaign in which it finished second in a step by step comparison between itself, Toyota, Datsun and the Rabbit; yet sales increased significantly.

Test Results. Another major question involves the use of test results. How conclusive must the tests be in order to deem them significant? Should the results and test design be made available to anyone who wants them? Also, the consumer might not be able to identify which product is being promoted in a comparative advertisement. This could cause a boomerang effect, thereby increasing the competitor's sales.

Product Market. Finally, the product and target market become important. Certain product/market factors may lend themselves better to comparative advertising than others. As illustrated previously, drug goods and consumer household goods are already using the comparative advertising tool to a greater degree than other products in the television media.

Techniques

Directionality. Pride, Lamb, and Pletcher have exposed one strategy that they refer to as ***directionality.***[14] This term describes whether the product is associated with, or differentiated from, the competing brand. An example of association is the Volvo advertisement that compares prices of the Volvo 164 with a Mercedes-Benz 250. The purpose is to [illegible] the Volvo's image by associating it with the Mercedes, while emphasizing the Volvo's more affordable price. Differentiation can be demonstrated by another automobile comparison advertisement. A Saab is compared to a Volvo on a number of criteria. The advertisement differentiates the cars using twenty-eight separate attributes.

Stressing Attributes. Another strategy involves changing the consumers' perceptions of specific attributes. The advertiser tries to emphasize positive product attributes. Mazola's advertising campaign probably illustrates this best. Initially, Mazola introduced the attribute of 100 percent corn oil and emphasized that Mazola margarine was the only product using pure corn oil. Then, corn oil was built up in the consumers' minds by playing up all of its advantages over other oils. Finally, comparative advertisements were used to clarify that Mazola is the only one of the three leading oils that is 100 percent corn oil.

The Challenger. Many times a very small advertiser will challenge the major advertiser in a field. The purpose of this is to bring attention to the advertisement because the major brand is already well known. A current example of this is Shasta Cola, a cola with only a small share of the market, comparing its taste to that of the two giants, Coke and Pepsi. At the end of the advertisement a man says, "If I were those other two colas, I'd watch out!"

One final strategy is name clarification. A classical example of this is the Goodrich Tire Company's advertising campaign designed to differentiate themselves from Goodyear Tire Company since their names are so similar.

EFFECTIVENESS

The effectiveness of comparative advertising is important both to the public and to the advertiser. Several questions still need to be answered about comparative advertisements.

Are comparison advertisements more informative, or are people just more likely to believe them simply because a comparison was made? Does comparison advertising lead to a clearer brand image, or can it backfire? Do the consumers' prior beliefs make a difference in comparison advertising effectiveness? If they already prefer or use the competing brand, what are the chances of swaying them over to the sponsor's brand? Could seeing their preferred brand in a comparison have a negative effect on their attitude toward the sponsor's product? Finally, does comparison advertising actually increase sales more than noncomparative advertising? Although several studies have been performed, the answers to these questions are not yet clear.

Generally, studies have shown no real differences between comparative and noncomparative advertising. Furthermore, "when interactions with other variables are not considered, comparative advertisements are no better or worse than" single product advertisements.[15]

Brand Recall and Loyalty

The ability of an advertisement to leave the viewer with a solid memory of the product is usually referred to as brand recall. In a study by Levine, respondents were exposed to a number of sets of commercials containing various mixes of comparative and noncomparative advertisements. After each set, they were asked to recall as many brands as possible. Generally, identification of brands was not dependent on type of advertisement. In one case where differences did exist, comparatively advertised brands were recalled less often.[16] In contrast, Prasad measured claim recall and found that subjects had a much higher memory of claims when comparative advertisements were viewed.[17] Perhaps, as Mazis' work indicates, this is because comparative advertisements are more active, aggressive, and interesting, thus causing higher awareness.[18]

When another brand is mentioned, the possibility always exists of misidentification of the sponsored brands. Levine's study supports this idea. Women exposed to comparative advertisements were significantly more likely to identify one of the competitive named brands as the sponsor brand than women exposed to noncomparative advertisements. This could lead to a higher awareness of the competitor's product than of the sponsored product.

If the consumer already prefers a brand, comparative advertising against it may cause negative attitudes toward the sponsored brand. Golden found that brand loyalty was very important when explaining the variance in purchase intention. It was found that the "degree of brand loyalty toward the sponsoring brand positively affects respondents purchase intentions."[19] Among subjects who had a prior preference for Kodak, Prasad found more negative attitudes toward a fictitious brand regarding claim credibility than among subjects who did not have a prior preference for Kodak. He then recommends that advertisers be extremely careful to adequately substantiate all claims in order to boost public confidence in their advertisement.[20]

Informative Value

Since information value was a prime reason for lifting the taboo on comparative advertising, it would be hoped that comparative advertisements are more informative than noncomparative advertisements. These direct comparisons give the consumer a specific standard with which to weigh purchase decisions between competing brands. Single product advertisements may not provide a basis for decision. A study by Pride, Lamb and Pletcher found that the effectivenes of comparative advertisements for producing feature awareness was not significantly different between the two types of advertisements. It was found, however, that moderately intense advertisements "create higher levels of perceived informativeness" than do low intensity advertisements.[21]

Persuasiveness

Along with informative value and brand recall, persuasiveness is a major concern to advertisers. Do comparison advertisements really persuade consumers to try a product? Again, Levine's study finds no significant increase in brand choice when the product was comparatively advertised. Specific commercials were found to be more persuasive than others, but this did not depend on whether the ad was comparative or not. Levine did find that persuasive value of a commercial increased significantly if it was the only comparative one shown in a group of commercials.[22] This suggests that novelty is a factor. As long as comparative advertisements remain a small part of total advertising, the persuasive value may be greater.

Studies basically show that negative attitudes are associated with comparative advertising. People are skeptical of advertisers' claims because they do not believe that the tests are conducted fairly. McDougall mentioned in his study, though, that there are a minority of respondents who did hold positive attitudes towards comparative advertising. He suggests that if this group can be defined, certain products may be targeted at them using comparative advertising campaigns.[23]

Successes

Despite the mounting evidence that comparative advertising is no better and at times has the potential to be worse than traditional advertising, success stories do exist.

One of these involves Savin Business Machines Corporation. Savin wanted to edge in on Xerox and IBM in the plain paper copier field. They felt they had developed a superior product that was actually less expensive than comparable Xerox or IBM models. The difficulty of competing with such well established firms called for an intensive campaign. Savin produced a campaign asking, "What do Xerox and IBM copiers have most in common? Both are most commonly replaced by the Savin 780." Sales have nearly quadrupled in the three years since the campaign began.

Another success story is the Schick Inc. Fleximatic electric shaver. Schick compared the Fleximatic to three of the leading shavers by name. Sales increased by 28 million, and the market share went up by about 16 percent. Success, however, is not always sweet. In Schick's case, legal suits total more than $12 million, and the advertising industry's self-regulatory bodies forced the advertisement to be taken out of the media. It was ruled that the advertising campaign was "false in some details and misleading in its overall implications."

The large number of formal complaints shows that the initial reluctance of the FTC to encourage comparative ads was well founded. Many lawsuits have been filed by firms whose products were named in comparative advertisements. Alberto-Culver, makers of Alberto Balsam creme rinse, filed a suit against Gillett asking $7 million in damages. They based their case on the fact that sales had fallen sharply after a false and misleading ad was shown in which Alberto-Balsam was named. In another case, the FTC filed suit against General Electric for inadequate proof that their television required less servicing than any other brand. G.E. had based several advertisements on this feature.[24]

CONCLUSION

Perhaps there are two perspectives from which to view comparative advertising: a public policy view and an advertiser's view. From a public policy perspective, several positive benefits can be derived from comparative advertising. If done fairly and honestly, the consumer may really benefit from the increased information allowing better buying decisions. Comparative advertisement may also encourage innovation and foster competition, also benefiting the consumer.

On the negative side, possibility of deception always exists. Perhaps the biggest problem is the opportunity to use only selective data in the advertisements. Few advertisers would communicate test results that were negative toward their own product. Test designs can be constructed so as to give the desired product an edge over the competitor. One solution to this problem is to create an independent test center that screens all comparative ad claims before they are released. This obviously would be very expensive. Another solution would be to have strict regulation and heavy penalties for deceptive ads and distorted test results. Another negative factor might be the possibility of consumer confusion caused by exposure to competing advertisements.

From the advertiser's viewpoint, comparative advertising may allow a small company to benefit from association with the industry leaders, may allow product benefits to be more clearly differentiated, and may force firms to be more progressive and innovative. On the negative side, there is a possibility of loss of credibility for the firm, a boomerang effect, and the questionable effectiveness of the technique.

When considering using comparative advertisements, a firm should follow Wilson's suggestions: First, nontrivial attributes must be compared. Second, well-documented evidence should be obtained on which to base all claims. Third, comparisons should be of a moderate intensity and among brands with which the advertiser directly competes. Finally, all measures should be taken to avoid sponsor misidentification. This includes displaying the sponsor's name prominently and early in the advertisement. If these cannot be met, the advertiser would do well, in light of available evidence, to follow a traditional type of advertisement.[25]

NOTES

[1] Aimee L. Morner, "It Pays to Knock Your Competitor," *Fortune* (February 13, 1978), pp. 104-111.

[2] *Ibid.*

[3] "Comparative Ads in Center Ring at AAAA Meeting," *Broadcasting* (May 17, 1976), pp. 42-44.

[4] *Ibid.*

[5] William L. Wilkie and Paul W. Farris, "Comparative Advertising: Problems and Potential," *Journal of Marketing*, 39 (October 1975), pp. 7-15.

[6] Morner, "It Pays."

[7] William L. Wilkie and Paul W. Farris, "Comparative Advertising: Issues and Prospects," Marketing Science Institute Working Paper (August 1974).

[8] *Ibid.*

[9] *Ibid.*

[10] William M. Pride, Charles W. Lamb, and Barbara A. Pletcher, "Are Comparative Advertisements More Informative For Owners of the Mentioned Competing Brands Than For Non-owners?" In Barnett A. Greenberg and Danny N. Bellenger, editors, *Contemporary Marketing Thought: 1977 Educators' Proceedings* (Chicago: American Marketing Association, 1977), pp. 298-301.

[11] Stephen W. Brown and Donald W. Jackson, Jr., "Comparative Television Advertising: Examining Its Nature and Frequency," *Journal of Advertising*, 6 (October 1977): 15-18.

[12] *Ibid.*

[13] Donald W. Jackson, Jr., Stephen W. Brown, and Robert R. Harmon, "Exploring the Dimensions of Comparative Magazine Advertisements," *Journal of Advertising Research*, forthcoming.

[14] Pride, et al., "Comparative Advertisements."

[15] R. Dale Wilson, "Comparative Advertising: Some Current Considerations For Managerial Planning and Strategy," *Current Issues and Research in Advertising* (Ann Arbor: Division of Research, Graduate School of Business Administration, The University of Michigan, 1978), pp. 5-22.

[16] Philip Levine, "Commercials That Name Competing Brands," *Journal of Advertising Research*, 16 (December 1976): 7-14.

[17] V. Kanti Prasad, "Communications — Effectiveness of Comparative Advertising: A Laboratory Analysis," *Journal of Marketing Research*, 13 (May 1976): 128-137.

[18] M. B. Mazis, "A Theoretical and Empirical Examination of Comparative Advertising," unpublished paper, University of Florida, 1976.

[19] Linda R. Golden, "Consumer Reactions to Comparative Advertising," In Beverlee B. Anderson, editor, *Advances in Consumer Research*, Volume 3 (Atlanta: Association for Consumer Research, 1976), pp. 63-67.

[20] Prasad, "Communications — Effectiveness."

[21] Pride, et al., "Comparative Advertisements."

[22] Levine, "Commercials."

[23] Gorden H. G. McDougall, "Comparison Advertising: Consumer Issues and Attitudes," In Barnett A. Greenberg and Danny N. Bellenger, editors, *Contemporary Marketing Thought: 1977 Educators' Proceedings* (Chicago: American Marketing Association, 1977), pp. 286-291.

[24] The authors acknowledge the assistance of Cynthia Hostetler, a Master of Business Administration student, in the preparation of this article.

[25] Wilson, "Comparative Advertising."

DEBATE PROPOSITION THREE

RESOLVED THAT: THE FEDERAL GOVERNMENT SHOULD ESTABLISH STANDARDS FOR TESTING AND MARKETING ALL PRODUCTS WITH POTENTIALLY CARCINOGENIC EFFECTS ON HUMANS

In recent years the Federal Government has increased its role in ensuring that the American public's safety and health are not impaired by the introduction or use of toxic substances in consumer products. The U.S. Congress has enacted numerous laws to establish the control of and protection from toxic substances not only in consumer products but also in air and water. These laws have included protection from exposure to substances that may cause cancer (carcinogens).

Laws to regulate toxic substances have been difficult to implement due to their reliance on scientific evidence to determine whether or not, among other effects, a substance poses a carcinogenic risk to humans. Science is not a static discipline. Its dynamic nature forces policymakers to make decisions based on "the best available evidence," and each of the laws enacted has included guidelines based on the state of scientific knowledge at the time when it was passed.

This piecemeal method of controlling exposures to hazardous substances has led to disparate and confusing methods to evaluate the risks of a substance's use in a variety of exposures. Some of the laws explicitly state how the risks associated with a substance must be weighed against the benefits derived from the use of that substance. The methods of testing, however, are left to the appropriate administrator to decide. Other laws allow regulators to determine only the risks associated with a substance: they allow no use of discretion by the regulators.

In the wake of public outcries over proposed regulation of such products as saccharin and nitrites, Federal regulators and the Congress are currently evaluating their policies and laws with regard to carcinogenic substances. The Federal agencies responsible for regulating toxic substances have moved to coordinate their criteria for determining the potential carcinogenic risk posed by a substance. The Congress has begun to explore alternatives to existing toxic substances laws.

Many issues have arisen in these efforts to set standards for testing and marketing products which contain substances with carcinogenic properties. These questions include: (1) Should Congress amend or repeal current laws requiring absolute safety in the marketing of consumer products? (2) Have these laws become outmoded due to further advances in scientific knowledge? (3) Should Congress make policy judgments in regard to risks associated with consumer products, or are these decisions better handled by scientists? (4) Who should be responsible for determining an acceptable level of risk of exposure to carcinogens--Congress or the Federal agencies? (5) Is standardization of testing substances for carcinogenic properties feasible, given the controversies over differences in sources of exposure, appropriate routes of administration, high-risk populations, extrapolation of experimental animal results to humans, and the inadequacies of epidemiological studies? These are some of the complex scientific and policy questions that need to be answered.

The following articles have been selected to illustrate several viewpoints on these questions. More general articles are also included for use as points of departure and background.

Controlling Toxics

By Truman Temple

Exactly 100 years ago Peter Collier, the chief chemist at the U.S. Department of Agriculture's Division of Chemistry, decided to do something about the rampant adulteration of foods in the United States. A hedgepodge of State laws provided scant protection. Collier saw the need for Federal action and drafted a bill to provide it.

During the next 25 years more than 100 bills were introduced in Congress to cope with the situation. A handful of measures were approved around the turn of the century dealing with the problem in piecemeal fashion, but the most significant action came in 1906 with enactment of the Food and Drug Act and the Meat Inspection Act.

These were the first important Federal laws in this country dealing with "toxic substances," for they sought to prevent the distribution of consumer products that contained, for one reason or another, some very potent poisons. Prompted in part by illness and death among U.S. troops who had eaten contaminated meat during the Spanish-American War, and later by a series of articles and books on abuses in the meat-packing and patent medicine industries, the laws enabled the government to proceed in Federal courts against injurious food preservatives. They halted numerous abuses in patent-medicine traffic. They prodded food processors into seeking better sanitation and sterilization. But the growth of many industries in the 20th century involving chemicals made it clear that other legislation would be needed and the Federal Government's regulatory role broadened. The Federal food, drug, and cosmetic law was rewritten in 1938 and subsequently amended several times. In addition, many other laws dealing with toxic materials of one kind or another were enacted. Ultimately, five major Federal agencies were created to administer some 15 different laws on the subject of toxic materials.

By far the most active period for legislation was the decade of the 1970's. Measures enacted by Congress during this period have been prompted by widespread public concern over environmental damage, by the consumer protection movement, by lawsuits, and by advances in medicine that stressed the need for preventive steps to shield the public from harmful chemicals, rather than costly clean-up activity after the damage has been done. Part of this philosophy reflected a shift in emphasis within the medical profession in dealing with cancer. Many physicians and research professionals felt that more emphasis should be placed on keeping carcinogens out of man's environment rather than on the "cancer cure" approach. Buttressing this view was the widely-circulated Surgeon General's report that had linked cigarette smoking with lung cancer, heart disease, and other ailments.

The Environmental Protection Agency has played a prominent role in administering many of the new laws dealing with various aspects of toxics since EPA's creation in 1970. The most directly involved of these laws, of course, are the Toxic Substances Control Act (TSCA) and the Resource Conservation and Recovery Act, both enacted in 1976. Others also dealing with toxics are the Clean Air Act, the Clean Water Act, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1972, and the Safe Drinking Water Act of 1974. (Control of toxics under the Clean Air Act is described elsewhere in this issue.)

One of the first problems that confronts someone grappling with this arcane subject is: What is toxic? From a medical point of view, just about everything is if taken in large enough quantities. As the 16th century physician, Paracelsus, has put it, "All things are poisonous, for there is nothing without poisonous qualities. It is only the dose which makes a thing poison." It is because toxics can be so broadly defined, and are so pervasive in our advanced technology, that many agencies and laws are involved in controlling them. However, much of the focus in identifying and controlling toxic substances today is on those that may cause chronic and irreversible health effects like cancer, birth defects, and gene mutations.

(Radioactive materials, though they may be highly toxic to humans, are handled under separate laws for a number of reasons. For purposes of definition, excess radiation is considered a physical insult to the body, while toxic substances are chemical insults. Also, a person may be harmed by radioactive material simply by proximity to it, whereas a toxic chemical would have to be ingested, inhaled or touched by a person to cause harm.)

EPA's task in regulating toxics is complicated by the vast numbers of chemicals that have come into the marketplace in the past three decades. Steven D. Jellinek, Assistant Administrator for Toxic Substances, has pointed out that TSCA empowers EPA to gather basic information on roughly 40,000 commercial chemical substances being made or processed by some 115,000 establishments.

Briefly, the law provides EPA with authority to do these things:

- Review new substances before they are manufactured to identify and prevent unreasonable risks;
- Require reporting of any significant new uses of existing chemicals and limit or prohibit any uses that might pose unreasonable risks;
- Require industry to test certain chemicals and categories of chemicals for adverse health and environmental effects;
- Control the distribution and disposal of any that pose an unreasonable risk to human health and the environment.

As required by TSCA, EPA last June released the Nation's first comprehensive inventory of commercial chemicals manufactured or imported into the United States during the past four years. The list will be updated periodically. An idea of the rapidity with which the whole chemical field is changing and growing is indicated by the number of chemicals on this initial list: 43,278 compounds manufactured or imported by 7,420 organizations since January, 1975.

Continued

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The Resource Conservation and Recovery Act deals with toxics when they are in the form of hazardous wastes being disposed of by society. The 1976 law directs EPA to identify hazardous wastes, taking into account such factors as toxicity, persistence, degradability, potential for accumulation in tissue, flammability and corrosivity. Permits are required for facilities treating, disposing, and storing such wastes. EPA is developing comprehensive regulations for hazardous waste management including guidelines for the development of State hazardous waste management programs. The Act also authorizes EPA and State officials to inspect facilities, copy records, and obtain samples to enforce requirements.

The Clean Water Act controls discharges of toxic pollutants into waterways and lakes by means of effluent standards. Under the earlier 1972 Federal Water Pollution Control Act, EPA established strict limits on the discharge of such toxic pollutants as toxaphene, endrin, PCB's, and benzidene. In addition, under the Clean Water Act, any industry that discharges its wastes into a municipal treatment plant must pre-treat its effluent so that it does not interfere with the plant's operation. (A more detailed article on this subject appears on page 17 in this issue.) EPA published a list of 65 toxic pollutants last year and may add to the list, as authorized by the law. Each toxic pollutant listed is subject to effluent limitations, using best available technology for clean-up.

Finally, the Safe Drinking Water Act of 1974 provides for the protection of drinking water supplies from intrusion by toxic wastes through national drinking water quality standards. The Act calls for studies of contamination by cancer-causing chemicals, a task in which EPA's laboratories play a major role.

Federal regulation of toxics, however, is not wholly the responsibility of EPA. In addition to the Food and Drug Administration, which administers the Federal Food, Drug and Cosmetic Act, and the Fair Packaging and Labeling Act, there are several other agencies involved in toxics.

The Department of Labor's Occupational Safety and Health Administration (OSHA) has responsibility for setting permissible levels of exposure for toxic substances in the workplace. It enforces these levels through workplace inspections and provides training and education concerning dangers posed by toxics to workers. The major law under which OSHA functions is the Occupational Safety and Health Act of 1970.

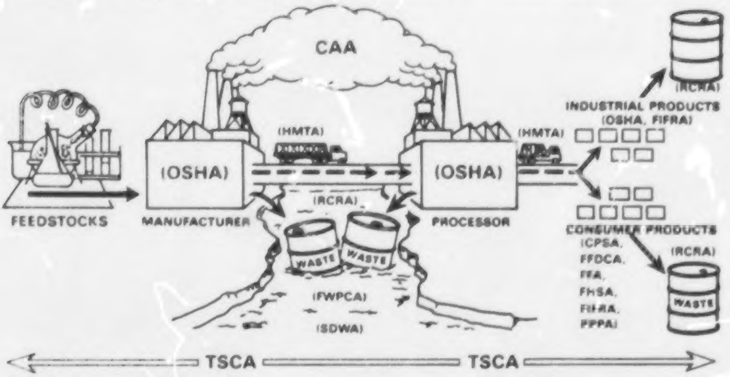
The Consumer Product Safety Commission is responsible for protecting the public from unreasonable risks of injury from consumer products, some of which may be chemical. The Commission derives its authority from the Consumer Product Safety Act of 1972, the Federal Hazardous Substance Act and the Poison Prevention Packaging Act of 1970, and some other laws less closely related to toxic substances.

Also, the Food Safety and Quality Service, established by the Secretary of Agriculture in 1977, oversees the quality of meat, poultry, eggs, and egg products to assure that they are safe to eat and properly labeled.

Other Federal agencies also have a hand in the way toxic substances are managed (see box). The Department of Transportation, for example, administers the

Continued to page 19

LEGISLATIVE AUTHORITIES AFFECTING THE LIFE CYCLE OF A CHEMICAL



• KEY •

CAA – CLEAN AIR ACT
CPSA – CONSUMER PRODUCT SAFETY ACT
FFDCA – FED. FOOD, DRUG, & COSMETIC ACT
FFA – FLAMMABLE FABRICS ACT
FHSA – FED. HAZARDOUS SUBSTANCES ACT
FIFRA – FED. INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT
FWPCA – FED. WATER POLLUTION CONTROL ACT
HMTA – HAZARDOUS MATERIALS TRANSPORTATION ACT
OSHA – OCCUPATIONAL SAFETY & HEALTH ACT
PPPA – POISON PREVENTION PACKAGING ACT
RCRA – RESOURCE CONSERVATION & RECOVERY ACT
SDWA – SAFE DRINKING WATER ACT
TSCA – TOXIC SUBSTANCES CONTROL ACT

TV Documentary on Toxics Available for Public Television

The Southern Education Communications Association, under a grant from EPA's Office of Public Awareness, has produced a one-hour television documentary on toxic substances titled "Serpent Fruits."

SECA is a public education network of 100 stations in 16 southern States. The film was linked to the Public Broadcast System satellite in June and thereby made available to all public television stations in the country for either simultaneous broadcasting or taping for later use.

"Serpent Fruits" documents the case histories of three individuals whose lives have been dramatically affected by chemicals. The first is a woman who was stricken with cervical cancer and had to have a hysterectomy at the age of 21 because her mother had used a drug called DES to prevent miscarriage during pregnancy.

The second describes the case of a young woman who suffered miscarriages, each within two months of the spraying of the herbicide 2,4,5-T near her residence in the Oregon forests. Over the years she had four miscarriages. After use of this herbicide was suspended in that State she gave birth to a normal son.

The third history concerns a former employee in a plant that manufactured polybrominated biphenyls (PBB's) and who did not use a mask, coveralls, or other protective measures. Two years ago he had to leave work because he was too weak to stand up. In describing his failing health, he wryly remarks that his body contained so much PBB that if he were a cow, he would be shot by the State of Michigan.

The film also features discussions by scientists and industry representatives of the validity of applying animal test results to humans and the difficulty of balancing risks against benefits in society's attempts to regulate toxic substances.

The film was produced by the prize-winning firm of Richter McBride Productions, Inc. of New York. Writer-producer was Robert McBride.

The television documentary was accompanied by the distribution in supermarket racks in June of a League of Women Voters' pamphlet entitled "A Toxic Substances Primer." A one-half hour version of the documentary is being made available as a 16 mm. film to schools and community organizations through Modern Talking Picture Service, Inc., 2323 New Hyde Park Road, New Hyde Park, N.Y. 11040. □

Federal Laws Dealing with Toxic Substances

Statute	*Responsible agency*	*Sources covered*
Toxic Substances Control Act	EPA	Requires premanufacture evaluation of all new chemicals (other than food, food additives, drugs, pesticides, alcohol, tobacco); allows EPA to regulate existing chemical hazards not sufficiently controlled under other laws.
Clean Air Act	EPA	Hazardous air pollutants
Federal Water Pollution Control Act	EPA	Toxic water pollutants
Safe Drinking Water Act	EPA	Drinking water contaminants
Federal Insecticide, Fungicide, and Rodenticide Act	EPA	Pesticides
Act of July 22, 1954 *(codified as § 346(a) of the Food, Drug and Cosmetic Act)*	EPA	Tolerances for pesticide residues in human food and animal feeds
Resource Conservation and Recovery Act	EPA	Hazardous wastes
Marine Protection, Research and Sanctuaries Act	EPA	Ocean dumping
Food, Drug and Cosmetic Act	FDA	Basic coverage of food, drugs, and cosmetics
Food additives amendment	FDA	Food additives
Color additive amendments	FDA	Color additives
New drug amendments	FDA	Drugs
New animal drug amendments	FDA	Animal drugs and feed additives
Medical device amendments	FDA	Medical devices
Wholesome Meat Act Wholesome Poultry Products Act	USDA USDA	Food, feed, and color additives and pesticide residues in meat and poultry
Occupational Safety and Health Act	OSHA	Workplace toxic chemicals
Federal Hazardous Substances Act	CPSC	"Toxic" household products (equivalent to consumer products)
Consumer Product Safety Act	CPSC	Dangerous consumer products
Poison Prevention Packaging Act	CPSC	Packaging of dangerous children's products
Lead Based Paint Poison Prevention Act	CPSC	Use of lead paint in federally assisted housing
Hazardous Materials Transportation Act	DOT (Materials Transportation Bureau)	Transportation of toxic substances generally
Federal Railroad Safety Act	DOT (Federal Railroad Administration)	Railroad safety
Ports and Waterways Safety Act Dangerous Cargo Act	DOT (Coast Guard)	Shipment of toxic materials by water

Controlling Toxics

Continued from page 15

Hazardous Materials Transportation Act
Last year DOT held hearings jointly with EPA in a move to integrate some provisions of the Act with the Resource Conservation and Recovery Act.

The many laws and regulatory agencies governing toxics have raised concern both in industry and government over the complexities of administration. In response to this problem, a cooperative agreement two years ago created the Interagency Regulatory Liaison Group (IRLG), which now pools the knowledge and resources of five Federal agencies working to control hazardous exposure to toxics throughout our society.

The group consists of EPA, OSHA, FDA, the Consumer Product Safety Commission, and the Food Safety and Quality Service. The formation of this coordinating unit was in direct response to a promise by President Carter to eliminate costly waste and duplication in government.

Through the IRLG, the five agencies are developing compatible testing guidelines and a common approach to the problem of assessing cancer risks posed by toxic substances. When possible, they are coordinating their research as well as their efforts to keep the public informed about hazards to health and safety.

An example was a report, "Hazardous Substances," issued late last year describing actions four of the agencies are taking to protect workers and the public from illness caused by unsafe manufacture and handling of 24 chemical compounds.

"Our cooperative efforts," explained Dr. Eula Bingham, Assistant Secretary of Labor for OSHA, "mean that the government's left hand now knows what the right is doing about these compounds. Instead of duplicating one another's work or perhaps even laboring at cross purposes, we'll be sharing information and research, issuing complementary standards, and conducting joint economic studies to control the dangers from radiation, heavy metals, and pesticides."

Another example of interagency coordination was joint action by EPA, OSHA, and FDA in 1977 to protect farmers, workers and the general public from possible dangers of the pesticide dibromochloropropene (DBCP). The agencies set emergency temporary standards to limit worker exposure, proposed suspension of crop applications and other uses, and monitored food to make sure the public was not consuming unsafe amounts of the substance.

The IRLG carries out its coordination at the Headquarters level in several ways. The heads of the agencies and other senior agency officials meet frequently, and a special senior staff group oversees coordination efforts. Interagency work groups and task forces deal with specific issues and projects.

As Administrator Douglas Costle commented on the IRLG's operations, "The result has been an effective task force which will develop testing standards and guidelines, conduct epidemiological studies and risk assessment, and share information. Our goal is to act as one entity in addressing important life-threatening issues." ☐

Truman Temple is Associate Editor of EPA Journal.

An Overview of How the FDA Regulates Carcinogens Under the Federal Food, Drug, and Cosmetic Act

By EDWARD J. ALLERA

Mr. Allera Is Associate Chief Counsel for Food, Food and Drug Administration, Department of Health, Education and Welfare.

I. INTRODUCTION

THE FOOD AND DRUG ADMINISTRATION (FDA) regulates three principal categories of products: food, drugs, and cosmetics; and the agency encounters and consequently regulates carcinogenic substances in each category and in the numerous subcategories of these products. As with the carcinogens, the statutory provisions by which the FDA regulates these substances are varied. The most noted is the "Delaney Anticancer Clause," but the Federal Food, Drug, and Cosmetic Act actually contains three Delaney Clauses. And these clauses apply only to three product subcategories: food additives, color additives, and new animal drugs. The Federal Food, Drug, and Cosmetic Act provides a scheme of premarket safety review by the FDA for these products. But the FDA regulates many products that are not subject to premarket review by the Agency that may contain a carcinogenic substance and that are not subject to a Delaney Clause, such as cosmetics, drugs subject to the over-the-counter (OTC) drug review, and food with added poisonous or deleterious substances such as aflatoxins. Conversely, it regulates one group that is subject to premarket approval but not a Delaney Clause—new human drugs.

Therefore, regulating carcinogens under the Federal Food, Drug, and Cosmetic Act is not simply a matter of concluding that a test

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compound is a carcinogen in test animals and, without more, banning the substance from food, drugs, and cosmetics. Many more issues must be considered and decisions made. To illustrate the intricacies and the inconsistencies of dealing with carcinogens under the Act, I will begin with a discussion of the Delaney Clauses and then proceed to a discussion of the other criteria and procedures that the FDA uses to regulate carcinogens in foods, drugs, and cosmetics.

II. LEGISLATIVE HISTORY OF THE DELANEY CLAUSE

The Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 301 *et seq.*, is a remedial statute designed to protect consumers and the public from dangerous products, and one fundamental aspect of this public protection function is to assure that all food additives, new drugs, new animal drugs, and color additives[1] are rigorously tested by their manufacturers and found to be safe by the FDA before the public is exposed to these articles or to food containing them. The basic Act was passed in 1938 without these provisions for premarket testing. Rather, it prohibited the use of "any poisonous or deleterious substances in food which may render it injurious to health" and prohibited recommending a drug for any use for which it is "dangerous to health." As a result, Congress has amended it several times, specifically to deal with the issue of safety of food to man, and each amendment has had the same underlying rationale, that is, to protect the public from the addition of articles to food that have not been shown to be safe by appropriate tests before they are marketed.

A. Food Additives Amendment

In 1958, Congress enacted the Food Additives Amendment (Public Law No. 85-929) to protect consumers by requiring substances that are intentionally added to food, or may reasonably be expected to become components or otherwise affect the characteristics of food, to be shown to be safe through rigorous scientific testing procedures. As the legislative history of the Amendment demonstrates, one primary function was to protect the health of consumers by requiring manufacturers of food additives and food processors to test any potentially unsafe substances which are added to food.[2]

Before the Amendment, the FDA's authority for action was limited to Secs. 402(a)(1) and (2)(A) of the 1938 Act, where it has the burden of showing that an intentionally added food substance may be injurious to health. This required the Agency to test the poisonous or deleterious substance before taking action. Therefore, the Amendment shifted both the burden of testing and proof of safety to the proponent of the additive. When the Interstate and Foreign Commerce Committee reported the bill to the full House, the bill did not contain an anticancer clause, but it did contain a specific section requiring the premarketing testing of food additives to demonstrate "safety," which is now known as the general safety provision.[3] After the bill was reported out, Congressman Delaney suggested the addition of the anticancer proviso to the bill, and the following proviso was added to the bill as a Committee amendment on August 13, 1958:

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[1] 21 U. S. C. 321(p), (s), (t), and (w).

[2] H. R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958).

> *Provided* that no additive shall be deemed to be safe if found to induce cancer when ingested by man or animal, or if it is found, after tests that are appropriate for the evaluation of the safety of food additives to induce cancer in man or animals.[4]

Reportedly to assure enactment of the legislation, the Committee and the Department of Health, Education, and Welfare (HEW) agreed to the amendment, but in a letter to the Chairman of the Committee, then Assistant Secretary Elliot L. Richardson noted that the amendment did not change the meaning of the bill. The letter also illustrates the interaction between the general safety and anticancer provisions of the bill and the broad scope that the Delaney Anticancer Clause is to be given.

> This Department is in complete accord with the intent of these suggestions—that no substance should be sanctioned for use in food that might produce cancer in man. H. R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions of use. This would afford good, strong public health protection.[5]

B. Color Additive Amendments

The Color Additive Amendments (Public Law No. 86-618) were added to the Federal Food, Drug, and Cosmetic Act in 1960. These

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[3] 21 U. S. C. 348(c)(3)(A).

[4] C. W. Dunn, Legislative Record of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, p. 52 (1958 ed.) *citing* Congressional Record of August 13, 1958, 85th Cong. 2d Sess. (1958).

[5] *Id.* at 40.

Amendments require sponsors of color additives to demonstrate the safety of these additives before they can be approved by the FDA for addition to food, drugs, and cosmetics in accordance with the provisions of Sec. 706 of the Act (21 U. S. C. 376). In addition, the Amendments added another Delaney Anticancer Clause to the Act which is found in Sec. 706(b)(5)(B) (21 U. S. C. 376(b)(5)(B)).

The legislative history of the Color Additive Amendments describes the Congressional and executive (Department of HEW) concern about the potential carcinogenicity of these color additives; nevertheless, the Secretary of HEW again explained that an express anticancer clause was unnecessary to prevent approval of carcinogenic or potentially carcinogenic color additives because the general safety and anticancer provisions of the bill provide the same scope of public protection.[6] During the House hearings, the Secretary also recommended the modification of the existing anticancer clause in Sec. 409 of the Act (21 U. S. C. 348) for food additives and the proposed anticancer clause in the color additive bill to permit the use of carcinogens in animals so long as no residues appear in any edible portions of animals. The Secretary, however, added two explicit caveats. The FDA would prescribe the reasonable but sound criteria for analytical methods to assure that no residues of the compounds will occur in food derived from food-producing animals given additives, and the industry would retain the responsibility of developing adequate analytical methods for detecting residues and furnishing the assay methods to the government.[7]

Therefore, as enacted, the safety provisions of the Color Additive Amendments are basically identical to the Food Additives Amendment. A color additive shall be deemed unsafe, within the meaning of the various sections of the Federal Food, Drug, and Cosmetic Act for use in food, drugs, and cosmetics unless the Commissioner has issued a regulation which states that the additive has been found to be suitable and safe for a particular use. The sponsor has the burden of establishing the additive's safety. Although the Commissioner can exercise his scientific judgment in determining whether safety has been proved, he is expressly precluded from listing any additive for any use that has been found to induce cancer in man or animals.[8]

But the statute also contains a transitional provision that provides for the continued use of commercially established additives to the extent consistent with the public health. The provision is transitional pending completion of the scientific investigations needed as a basis for making determinations on the safety of the additive for permanent approval. The provisional list was to expire on January 12, 1963, or such later date as the Commissioner determined necessary consistent with the objective of carrying to completion, in good faith and as soon as practicable, the investigations needed for making the safety determination. The Commissioner has extended that date several times over the past decade while concurrently establishing testing requirements and periodic reports to assure that there is an orderly test ongoing that will resolve the safety questions.[9] Technically, the provisionally listed colors are not covered by a Delaney clause.

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[6] H. R. Rep. No. 2464, 86th Cong. 2d Sess. 1960.

[7] *Id.*

[8] *Certified Color Manufacturers Ass'n v. Mathews*, 543 F. 2d 284, 287 (CA DofC 1976).

C. Drug Amendments of 1962

The livestock industry expressed increasing concern about the problems caused by the anticancer clause in the food additive provisions because the FDA had interpreted the Food Additives Amendment of 1958 to require continuation of approval for diethylstilbestrol (DES) for use in cattle and sheep, but to preclude new approvals of this drug.[10] In 1962 Congress was also considering legislation, which later became the Drug Amendments of 1962 (Public Law No. 87-781), to strengthen the FDA's ability to regulate the drug industry, and the Senate version of the bill was passed without considering any amendments to the Delaney Clause. The House Committee on Interstate and Foreign Commerce, however, included the current modifications of the anticancer clauses in its report on the Drug Amendments of 1962, with the following explanation:

> The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.[11]

Representative Sullivan objected to the proviso in the floor debate on the amendments and proposed a separate amendment to delete the proviso from the bill because "they [the provisos to the Delaney clauses] weaken instead of strengthen consumer protection." She reminded the House that DES had been regarded as safe for use in poultry at one time because no residue was found in the meat; subsequently, that use had to be terminated when DES residues were found as a result of improved testing methods. But her amendment was defeated principally on the argument that if DES were available for manufacture by those who obtained approvals prior to 1958, it should be made available for manufacture by everyone.[12]

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[9] 42 *FR* 6942. *Health Research Group v. Califano*, Civil Action No. 77-293 (D.D.C. Sept. 23, 1977).

[10] Study of the Delaney Clause and Other Anticancer Clauses, Hearings Before a Subcomm. of the House Comm. on Appropriations, 93rd Cong., 2d Sess., pt. 8, 205 (1974).

[11] *Id.* at 206.

The Senate accepted the modifications to the Delaney Clauses in conference while preserving, as Senator Humphrey noted, the full vigor of consumer protection afforded by the Delaney Clause.[13]

D. Animal Drug Amendments of 1968

Because the animal feed industry experienced an era of unprecedented growth and innovation beginning in the 1950's, that industry and the animal drug industry began an effort in the mid-1960's to consolidate the various provisions of the Federal Food, Drug, and Cosmetic Act governing the premarketing approval of drugs intended for use in animals, that is Secs. 409, 505, 507 (21 U. S. C. Secs. 348, 355, and 357) which culminated in the enactment of the Animal Drug Amendments of 1968 (Public Law No. 90-399). Neither the Committee reports on the bill nor the floor debates raised the issue of the Delaney Clause. Consequently, the Animal Drug Amendments passed without controversy and contained the following anticancer clause and proviso:

> (H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the following provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals; (Sec. 101(H) Public Law No. 90-399).

Again the legislative history indicates that the legislation in no way weakens the FDA's authority to regulate new animal drugs.[14]

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[12] *Supra* note 10 at 206-207.

[13] 108 Cong. Rec. 22053.

[14] S. Rep. No. 1308, 90th Cong., 2d Sess. 1968.

E. Conclusion

Thus, the Delaney Anticancer Clause has been added to the Federal Food, Drug, and Cosmetic Act three separate times, and the proviso to that clause has been enacted twice. Through all these reenactments, the purpose of the clause has remained unchanged. Each article covered is to be rigorously tested for carcinogenic potential before it can be approved for use. Carcinogenic, or potentially carcinogenic food additives and color additives are not to be approved for human use, and no article can be approved for use in food-producing animals unless the Secretary designates an assay method which will assure that no carcinogenic residue of the article will be found in food derived from food-producing animals that are given the drug. Finally, the criteria and procedures used to designate the assay method must be sufficiently comprehensive to protect the unwary public from any significant risk of cancer from the undetected residues of any article.

Nevertheless, several problems exist under the Delaney Clause which exemplify the problems the FDA faces in regulating carcinogens under the other provisions of the Act. Foremost, of course, is the DES proviso. No matter how rigorous the FDA's assay evaluation and approval process, it is a fundamental law of analytical science that for every assay there is some lowest concentration below which limit the assay will not yield an interpretable response. Other than ingestion tests, Congress has provided no guidance as to what constitutes appropriate tests for carcinogenesis, or what actually constitutes a carcinogenic response. These problems also exist for ingestion tests. Lastly, Congress has exhibited a continued fondness for familiar carcinogens versus new ones, *e.g.*, under Secs. 201(s)(4), 402 (a)(1), and 406 of the Act.

With this in mind, let us now look at how the FDA is regulating carcinogens. Because questions about regulating carcinogens arise in the three basic groups of products that the FDA regulates, I will focus on foods, drugs, and cosmetics for the sake of simplicity rather than approaching the review strictly by statutorily defined articles.

III. FOODS

A. Introduction

By far the most labyrinthian category is foods because it is subject to regulation under several statutory provisions with differing rationales, legal standards, and procedures. Essentially, the regulated food ingredients can be divided into three groups based on their sources:

1. Natural constituents, such as Vitamin C in orange juice;
2. Unavoidable contaminants, such as aflatoxin in corn;
3. Intentionally added substances that become or may be reasonably expected to become components of food due to their intended use, for example, saccharin, acrylonitrile monomers, DES.

B. Natural Food Constituents

The Delaney Clause is inapplicable to natural constituents of foods, even if they are found to cause cancer in test animals. Therefore, a food naturally containing a constituent that may be carcinogenic is not automatically banned by the Act, for example, safrole in nutmeg. These foods are regulated by Section 402(a)(1) of the Act. Such a food is adulterated if

> [i]t bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health....

This section has been interpreted by the courts; and under these decisions the FDA must demonstrate that the amount of a naturally occurring poisonous substance is sufficient to render the food in which it appears potentially unsafe for consumption. A showing of a reasonable possibility of causing harm to some segment of consumers is sufficient to support a charge of adulteration, but the risk must be more than a speculative one.[15] Thus, although the FDA might contend that any amount of such a nonadded, that is, constituent, carcinogen is unsafe for at least a smaller number of consumers, the case law and language suggests that the Agency must show a potential harm to a segment of consumers above the normal "background level of consumption."[16]

Historically, the FDA enforces Sec. 402(a)(1) principally through seizure or other court action because there is no legal mechanism for requiring the distributor of such food to seek prior FDA approval of the safety of the food or its constituents. Nor does the statute provide a procedure for administratively withdrawing permission to market foods with these naturally unsafe constituents, although the

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[15] *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399 (1914).

[16] Cf. *Id.*: *United States v. 1,680,000 Pounds of White Corn* Civ. Action No. T-4173 (D. C. Kan., December 18, 1970); 21 U. S. C. 342 (a) (1).

FDA could use its rulemaking authority under Sec. 701(a) to administratively ban a food.

C. Unavoidable "added" food constituents

A second class of food constituents are those that, although not naturally occurring in the sense of being inherent, occur unavoidably in the harvesting or production of many foods, most of them agricultural commodities such as grains, fish, meat, or milk. The most prominent recent example is aflatoxin mold on peanuts and grains, well recognized as carcinogenic in both test animals and man. The FDA has recently completed a rulemaking procedure establishing a formal mechanism for regulating these constituents.[17]

Such unavoidable constituents are not subject to a Delaney Clause because the Food Additives Amendment is inapplicable to them for two reasons. First, although the FDA has treated such constituents as "added" within the meaning of Sec. 402(a)(1) of the Act, they cannot be approved at any level under Sec. 409 because they serve no functional purpose, and a food additive must be functional before it can be approved.[18] Second, the FDA has assumed that Congress did not intend Sec. 409 to apply to constituents whose addition to food, at least at some levels, is unavoidable. As the legislative history of the Food Additives Amendment clearly demonstrates, it was enacted to regulate ingredients added to food intentionally and to constituents, such as packaging materials, that become part of food through intentional use for other purposes.[19]

The apparent absolute adulteration, under Sec. 402(a)(1) of the Act, of any food containing any amount of an "added" poisonous contaminant, such as aflatoxins is modified by Sec. 402(a)(2)(A), which provides that a food shall be deemed to be adulterated: "If it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406 . . ."

Section 406 of the Act thus provides a basic framework within which the FDA can regulate toxic constituents, including carcinogenic chemicals, whose occurrence in some foods at some levels cannot be avoided, and the agency has established a mechanism to implement this provision.[20]

Essentially, the FDA is empowered to establish tolerances for unavoidable toxic contaminants of food, including contaminants that may be carcinogenic, and Sec. 406 prescribes two basic criteria for the FDA to use when establishing such a tolerance: (1) the level whose consumption will not pose an unacceptable risk to public health, taking into account other ways in which consumers may be exposed to the contaminant, and (2) the extent to which occurrence of the contaminant cannot be avoided through good manufacturing practice. If good practice can achieve lower levels than public health considerations would otherwise dictate, the FDA will presumably establish a tolerance at the lower level.

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[17] 21 CFR Part 109; 42 *FR* 52814; 39 *FR* 42743.

[18] 21 U.S.C. 348(c) (4) (B); 21 CFR Part 170.

[19] H. R. Rep. No. 2284, *supra;* 39 *FR* 42744.

[20] 21 CFR Part 109.

A third criterion, even though not explicit in the Act, is implicit in the FDA's ability to set tolerances—the measurability of the contaminant. Realistically, the FDA cannot enforce a tolerance that is below the level of detection or measurement of the best practicable method of analysis available

The Act prescribes elaborate formal rulemaking procedures for establishing tolerances under Sec. 406.[21] Partly because of the complexity of this procedure for establishing formal tolerances under Sec. 406, the FDA has established a system for prescribing so-called "action levels" for unavoidable, added contaminants in food by notice and these action levels are the levels of contamination which will cause the FDA to initiate court enforcement actions under Sec. 402 (a)(1).[22] The criteria establishing action levels and tolerances are basically the same, although the Agency will only establish an action when technological or other changes might affect the appropriateness of a tolerance in the foreseeable or near future.[23]

D. Substances that may reasonably be expected to become components of food or affect the characteristics of food.

There are five basic types of substances in this category: food additives (both direct and indirect), substances that are generally recognized as safe by qualified experts (GRAS), prior sanctioned substances, color additives, and new animal drug residues. All are food ingredients, but not "food additives" as defined by the Federal Food, Drug, and Cosmetic Act. The latter four types have been carved out of the statutory definition. Only three (food additives, color additives, and new animal drugs) are subject to premarket review and approval by the FDA, and only two of those (food additives and color additives) are covered by the flat prohibition imposed by the Delaney Clause, although GRAS substances are indirectly. Carcinogenic new animal drugs may be added to food if they satisfy the DES proviso to the Delaney Clause.

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[21] 21 U. S. C. 701(e).

[22] 21 CFR Part 109; 42 *FR* 52814, 39 *FR* 42738.

[23] Compare 21 CFR 109.6(b) and (c).

1. *Food additives*

a. Direct food additives.

A food additive is:

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended uses (21 U. S. C. 321(s)).

Before any such ingredient may lawfully be used, it must be the subject of an approved food additive regulation, and the FDA may not approve a food additive unless it satisfies two criteria. First, it must have been shown to be safe under the conditions of its intended use. This requires a demonstration that, with reasonable certainty, the additive will not have adverse effects on the health of consumers, and, second, it must also be shown to be functional, that is, a preservative must preserve when used at the levels intended. However, it is covered by the basic Delaney Clause which flatly prohibits the approval (or requires the withdrawal of any outstanding approval) of a food additive that has been shown to induce cancer in man, or, through appropriate tests, in animals. By statute, ingestion tests are always appropriate.[24]

The procedure for approving or withdrawing approval of a food additive is as complex as that for the establishment of tolerances under Sec. 406. It is a variant of formal rulemaking.[25]

b. Indirect food additives

A wide variety of materials are used in contact with food—such as food packaging and in equipment used to produce food—in such a fashion that small amounts may migrate to and become a part of the food. The Food Additives Amendment did not distinguish between ingredients used in making food and materials that migrate to food from food-contact surfaces.[26] The latter are colloquially known as indirect food additives.

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[24] 21 U. S. C. 348.

[25] *Id.*

The basic statutory criteria for approval are the same for indirect and direct food additives, and the procedures for obtaining, or withdrawing, approval are identical. The Delaney Clause therefore applies to indirect food additives, and effectively prohibits the use in applications that might migrate to food of any substance that has been shown to cause cancer in laboratory animals.

The FDA's most recent decision in this area is a case involving acrylonitrile copolymers used to fabricate beverage containers (42 *Federal Register* 48528). The Commissioner concluded that the acrylonitrile monomer may reasonably be expected to migrate and thus become a component of food using an extrapolation model, based on the principle of diffusion and confirmed by actual migration data even though the migration cannot be analytically detected.[27]

2. *GRAS substances*

Congress established an exception to the Food Additives Amendment for GRAS substances principally to exclude from the rigors of premarket review ingredients that have a long history of use in foods, without evident harmful effect, such as apples, salt, and sugar. The Act, however, provides no formal mechanism for determining GRAS status. It does however create two basic categories of GRAS substances: those currently recognized as safe based on their common use in food prior to 1958 and those recognized as safe by experts on the basis of tests conducted before or since 1958.[28]

The FDA has always acknowledged that a food manufacturer may initially determine for itself whether an ingredient is GRAS, although it runs the risk that the FDA will disagree and initiate regulatory action.[29] The regulations amplifying this section of the statute require quantity and quality of scientific procedures and evidence to attain GRAS status or are required to attain approved food additive status.[30]

Because GRAS ingredients do not fall within the statutory definition of food additives, they are not subject to the Delaney Clause. In practice, however, the Delaney principle prevents the introduction or continued use of a GRAS ingredient found to cause cancer when ingested by laboratory animals because such a finding will almost certainly destroy any basis for general expert recognition of an ingredient's safety and thereby render it a food additive. FDA approval is then required, and this would be precluded by the Delaney Clause. This is essentially what occurred to cyclamates in 1970.

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[26] 21 U. S. C. 321(s).

[27] 42 *FR* 42528.

[28] 21 U. S. C. 321(s).

[29] 39 *FR* 34194.

[30] 21 CFR 170.30.

Soon after the passage of the Food Additives Amendment, the FDA issued, and from time to time amended, a non-exclusive list of ingredients that the Agency was prepared to acknowledge as GRAS, and thus eligible for use without affirmative FDA approval. Because the Act makes no provision for the transition between GRAS status and approval as a food additive, the FDA has issued a regulation,[31] establishing procedures for issuance of interim food additive regulations. An interim food additive regulation may be issued for an ingredient whose safety is brought into question but whose continued use, pending the conduct of the studies necessary to resolve the safety issues, poses no significant risk to human health.

The FDA also has established a program for reviewing the safety of GRAS ingredients, and for "affirming" the GRAS status of individual substances.[32]

3. *Prior sanctioned ingredients*

The Food Additives Amendment also contains a grandfather clause for ingredients that the FDA or U. S. Department of Agriculture (USDA) had affirmatively approved prior to the effective date of the Amendment.[33] Although the FDA lacked formal authority to license food ingredients at that time, it responded to requests for opinions about the safety of individual ingredients. In addition, the USDA had issued regulations describing permitted uses of many ingredients in meat and poultry products, and in some instances the FDA had also formally acknowledged its sanctioning of certain substances for food use.

A prior sanctioned ingredient is permanently grandfathered, because it can never fall within the statutory definition of a food additive, at least for the purposes for which it was previously sanctioned, and therefore never becomes formally subject to the Delaney Clause. This means that a carcinogenic ingredient for which a prior sanction exists is not automatically forbidden to be used in food.

This does not mean that the FDA cannot prevent the use of a prior sanctioned ingredient that new evidence demonstrates to be unsafe. However, the Agency must be prepared to prove, ordinarily in court, that the presence of the ingredient renders food adulterated within the meaning of Sec. 402(a)(1). Accordingly, a finding that a prior sanctioned ingredient is a carcinogen might permit the FDA to prevent that ingredient's use but it would not mandate that action.[34]

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[31] 21 CFR 180.1.

[32] 21 CFR 170.35.

[33] 21 U. S. C. 321(s)(4).

4. *Color additives*

The statutory definition of color additives is broad, and the regulatory requirements are essentially similar to those applicable to food additives.[35] The sponsor must demonstrate the color's safety, and the Delaney Clause is applicable.[36] But because the Color Additive Amendments of 1960 have no provision for "generally recognized as safe" colors and do not exclude from the definition of color additive, the Delaney Clause applies to *all* such coloring agents.

Congress did, as noted above, authorize the FDA to "provisionally list" colors that were in use in 1960 and that were believed to be safe in order to permit the performance of the kind of toxicological testing required to support contemporary scientific judgments of safety.[37]

The provisional list thus represents a form of temporary grandfather clause, designed to permit an orderly transition from essentially unregulated use of colors to a scheme in which *all* color additives are licensed in the same fashion as food additives.

The statutory procedures for disapproving or withdrawing approval of a color additive parallel those applicable to food additives, with two important distinctions. First, if the FDA, after publishing a proposal and receiving comment, issues a final order terminating approval of a color, the filing of objections accompanied by a request for a hearing automatically stays the Agency's order pending the hearing.[38] Next, Sec. 706 also provides for a statutory advisory committee to review the evidence when the Agency proposes to withdraw approval of a permanently listed color due to carcinogenicity.[39] Provisionally listed colors, however, may be summarily delisted merely by notice.[40]

5. *New animal drugs*

The FDA's most sophisticated regulation of carcinogens occurs in the area of new animal drugs intended for use in food producing animals. Drugs are used in those animals for treatment and prevention of disease and for growth promotion, and the premarket review process is two tiered with the sponsor, of course, having the burden of proof. First, the FDA must determine whether the drug is safe and effective for use in the animals, analogous to the risk/benefit assessment used for new human drugs, which, prior to enactment of the Animal Drug Amendments of 1968, was the statutory provision under which this part of the data were reviewed. Then, the Agency reviews the safety data to assess the safety of the potential residues that may occur in food deprived from the treated animals using the food additive standard of safety, which was the governing statutory provision before 1968.[41]

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[34] 21 CFR 181.5; 39 *FR* 54195.

[35] 21 U. S. C. 321(t).

[36] *Certified Color Manufacturers Ass'n v. Mathews, supra* note 7 at 287; 21 U. S. C. 376.

[37] *Certified Color Manufacturers Ass'n v. Mathews, supra* note 7; *Health Research Group v. Califano, supra* note 8.

[38] Compare 21 U. S. C. 348(e) with 371(e) (1) and 376(c).

[39] 21 U. S. C. 376(b) (5) (C).

[40] *Certified Color Manufacturers Ass'n v. Mathews, supra* note 7 at 296-297.

Although these drugs are subject to the Delaney Clause, carcinogenic new animal drugs may be used in food-producing animals with two caveats: (i) the drug will not adversely affect the animals, and (ii) no residue of the drug will be found by methods of analysis designated by the Agency in any edible portion of the animal or food derived from that animal.[42]

As noted earlier, this language has practical limits, and it has caused the FDA numerous problems in evaluating the safety of new animal drugs.

However, in 1973, the FDA proposed to codify principles that had evolved from the Agency's grappling with the problem on a case-by-case basis. In the *Federal Register* of February 22, 1977, it promulgated an extensive procedure of assessing the designating assays, which is geared to a modified Mantel-Bryan statistical procedure for assessing the risk of any undetected residues.[43]

For all potentially carcinogenic new animal drugs intended for use in food-producing animals, the FDA's regulation established a six-step review procedure:

1. A threshold assessment to determine whether the sponsored compound or its metabolites requires carcinogenesis testing using all available chemical, biochemical, toxicological data. 21 CFR 500.80.
2. A comprehensive metabolite study of the sponsored compound in the target animal. 21 CFR 500.84.
3. Chronic toxicity testing in animals to measure the compound's carcinogenic potential. 21 CFR 500.87.

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[41] 21 U. S. C. 360b(d) (1); S. Rep. No. 1308, 90th Cong. 2d Sess. (1968).

[42] 21 U. S. C 360b(d) (1) (H).

[43] 42 *FR* 10412.

4. Application of the basic Mantel-Bryan procedure, with modifications developed by the FDA, to the data collected from the chronic carcinogenicity tests, in order to predict the risk of cancer associated with low levels of exposure to a carcinogenic compound. 21 CFR 500.87(b)-(d).

5. Specific criteria and procedures for evaluating and approving assay methods to assure no carcinogenic residues will occur in food. 21 CFR 500.80—500.90; and

6. A procedure for calculating withdrawal periods using the assay 99% confidence bounds on studies measuring the depletion of residues in the target animal. 21 CFR 500.92.

The new animal drug approval process is a licensing procedure, and the FDA must provide the applicants with notice and the opportunity for a formal hearing on its new animal drug application or proposal to withdraw approval of its application.[44] But they must demonstrate that material factual issues are in dispute before the FDA must grant a hearing.[45]

IV. HUMAN DRUGS

A. New Human Drugs

Basically, new human drugs, drugs that are not generally recognized as safe and effective by qualified experts,[46] are regulated in the same manner as new animal drugs.[47] They are subject to premarket approval; their sponsors have the burden of proving their safety, and the approvals grant private licenses. However, new human drugs are not subject to a Delaney Clause.[48] They are regulated through a general safety clause which permits extensive risk/benefit balancing both by the Agency and the prescribing physician since only the physician's patient will be directly affected by the drug's use, unlike the use of animal drugs in food-producing animals where many uninformed and perhaps unconsenting, individuals may be exposed to the drug. Many life saving drugs also have a carcinogenic potential, such as some of the antineoplastic drugs. Therefore, the risk of cancer from short term use of a drug for a life threatening or other important therapeutic use may be outweighed by the benefits provided by that drug. In those situations, it would be safe for use. As you can see, the normal rationales for regulating carcinogens are inappropriate in these cases.

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[44] 21 U. S. C. 360b(c) and (e).

[45] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U. S. 609 (1973).

[46] 21 U. S. C. 321(p).

[47] Compare 21 U. S. C. 355 with 21 U. S. C. 360b.

[48] 21 U. S. C. 355(d) (1) and (2).

The FDA also recently has taken a giant step in this area by mandating, through informal rulemaking, additional label warnings on the use of estrogens for general use.[49] It requires new warnings to physicians, and, more importantly, the FDA now requires drug manufacturers to provide the physician and pharmacist with labeling for the patients so that each patient can be and is fully apprised of the risk of such therapy.[50]

B. Old Drugs or OTC Drugs

For drugs that may be generally recognized as safe and effective, or drugs that are exempted by statute from the new drug application requirements, about which evidence of carcinogenicity becomes available, the FDA normally uses its general rulemaking authority to regulate.

First the Agency proposes to declare the article a new drug, setting forth the evidence upon which it has reached that decision in the notice. After evaluating comments, it then promulgates a final order declaring the article a new drug requiring approved new drug applications to market. The FDA proposes this action because the drug lacks sufficient benefit, and it requests manufacturers of new drug products containing the ingredients to be reformulated. Therefore, barring some new evidence of extraordinary benefit from the drug's use, the Agency essentially bans it.[51]

V. COSMETICS

A. General Ingredients

The FDA has bare bones authority to regulate carcinogens in cosmetics, that is, articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or part for cleansing, beautifying, promoting attractiveness or altering appearance, and articles intended for use as components of cosmetics.[52] The FDA has no premarket review authority, although it has such authority over color additives that are components of cosmetics. Therefore, while a Delaney Clause applies to color additives, neither Delaney nor a general premarket testing safety clause is available to regulate carcinogenic components of cosmetics.[53] The FDA is limited to statutory language and authority about adulteration that is identical to that applicable to added food substances.

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[49] 42 *FR* 37636 (July 22, 1977).

[50] 21 CFR 310.515.

[51] 21 CFR 310.513; 41 *FR* 26842.

[52] 21 U. S. C. 321(i).

[53] 21 U. S. C. 601, 602.

> Section 601. A cosmetic is deemed to be adulterated—(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to use under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual. . .

The FDA has construed this section quite broadly since it is the only authority the Agency has to protect the public. Using that in conjunction with its broad rulemaking authority, the Agency has banned from use in cosmetics ingredients that have been found to be carcinogenic by ingestion tests on rodents.[54] Therefore, it has concluded such tests demonstrate an unreasonable risk of harm at least for cosmetics that may be ingested and for cosmetics that are used topically, where there is evidence of absorption.[55]

B. Coal Tar Derivative Ingredients

The adulteration section for cosmetics also contains language that has been judicially construed to restrict severely the FDA's authority to regulate coal-tar hair dyes. Congress added a proviso that the section shall not apply to coal-tar hair dyes whose labeling bears a statutorily prescribed label warning that the product may cause skin irritation and bears adequate directions for preliminary testing for this potential problem.[56]

The FDA attempted to limit the exemption from adulteration to only those conditions that the statutorily prescribed warning specifically addresses. Unfortunately, the United States Court of Appeals for the Second Circuit concluded that coal-tar hair dyes labeled with the patch test warning are not adulterated no matter what their potential for harm since the FDA's position sought an enlargement of the statutory authority despite an apparently inadvertent congressional omission.[57] The FDA can, however, require additional label warning statements for cosmetics containing these ingredients through its general rulemaking authority to prescribe informative labeling.[58]

VI. CONCLUSION

The FDA's authority to regulate carcinogens in foods, drugs, and cosmetics is diverse. For noncoal tar dye cosmetics, at least its adequacy is uncertain, and its scope is untested by litigation. Clearly, the Delaney Clause is no panacea, although it represents a logical approach to a complex scientific issue because so many unknowns exist about cancer. The FDA has begun to use other procedures to deal with carcinogens, such as broader disclosure and statistical analyses of risks, but these approaches also pose problems. Can the public really understand the risk associated with the use, for example, of saccharin? Or is the Agency accurately assessing the risk associated with that use? There are no easy answers but full disclosure is the first step in conjunction with more extensive use of risk analysis. For the latter, I favor more regulations prescribing risk analysis, particularly in the areas of indirect food additives and cosmetic components.

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[54] 21 CFR 700.18; Prop. Reg. 21 CFR 700.12 (42 *FR* 20009).

[55] *Id.*

[56] 21 U. S. C. 601.

[57] *Toilet Goods Ass'n v. Finch*, 419 F. 2d 21, 29 (CA-2 1969).

[58] *Cosmetic, Toiletry, & Fragrance Ass'n v. Schmidt*, 409 F. Supp. 57 (D. D.C. 1976) aff'd on the basis of the District Court's opinion F. 2d (CA DofC 1976).

[The End]

REGULATORY COUNCIL

Statement on Regulation of Chemical Carcinogens; Policy and Request for Public Comment

AGENCY: Regulatory Council.

ACTION: Notice of Policy and Request for Public Comment.

SUMMARY: This policy is being published in the **Federal Register** to inform the public of the practices and principles the participating Federal regulatory agencies will follow in initiating regulatory actions relating to chemical carcinogens.

The Regulatory Council would welcome any comments from the public, particularly any additional information pertinent to these policies which may have been considered in the preparation of the statement.

Because much of the scientific basis for the policies on identifying chemical carcinogens and assessing human risk relies on the analyses and discussion in the document "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks," published at 44 FR 39858, July 6, 1979 (Annex B to this document), we request potential commenters to read that document carefully before commenting on the *scientific issues* addressed in the Regulatory Council's statement. We would further suggest that any comments on the substance of Annex B be addressed directly to that document which is currently undergoing public review and comment as well. The comment period on that document is being extended to October 31 by separate notice to allow additional comments to be received.

DATES: We would appreciate receiving comments by November 15, 1979, to ensure speedy consideration of additional public views.

ADDRESS: Mail comments to: Regulatory Council, Attention: Cancer Policy, Room 9002, New Executive Office Building, Washington, D.C. 20503.

Copies of this document including Annex B are available from: Industry Assistance Office, Office of Toxic Substances (TS-799), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460; or

Call toll-free 800/424-9065. In Washington, call 554-1404.

Signed in Washington, D.C., this 11th day of October 1979.

Peter J. Petkas,

Director.

Regulation of Chemical Carcinogens, September 28, 1979.

Statement on Regulation of Chemical Carcinogens

Introduction.
Determining Whether a Chemical Substance May Cause Cancer.
Assessing the Risk of Cancer to Humans.
Setting Priorities for Regulating Carcinogens.
Considering Regulatory Action.
Federal Agencies Having Primary Roles in the Regulation of Chemical Carcinogens, Annex A.
Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, Annex B.
Interagency Coordination Efforts Currently Underway Relevant to the Regulation of Carcinogens, Annex C.

Statement on Regulation of Chemical Carcinogens

Introduction

Cancer is a major national public health problem. Various kinds of cancer currently claim almost 400,000 lives per year, second only to heart disease, and a million people are under treatment for some form of the disease. One in four Americans—an average of almost one person per family—can expect to develop cancer in his or her lifetime, one in five will eventually die of it.

Cancer is also a substantial economic burden. The National Center for Health Statistics estimates that by 1977 the Nation was spending $5.3 billion each year on hospital care and physicians' services for cancer patients, and that the expected earnings of people who died that year had a value of $14.8 to $18.5 billion.

In addition, there are substantial social costs that are more difficult to quantify. The cancer victim may be disabled and in substantial pain even if he or she survives the disease. The victim's family may be left financially destitute and socially isolated, and may not recover from the psychological and economic costs related to the disease.

Encouraging advances are being made in treating some forms of cancer, so that more victims are now living five or more years after the disease is discovered. But progress in cancer treatment is slow because of the many gaps in our basic scientific knowledge about the disease.

The Nation, therefore, must make a particularly strong effort to prevent various kinds of cancer. With our present knowledge, this can be done most effectively by preventing the exposure of people to cancer-causing agents. There is substantial evidence that environmental factors are among the major causes of at least some kinds of cancer. Environmental factors include potential cancer-causing substances (called carcinogens) in food, air, drinking water, tobacco products, workplaces, drugs, and household products, as well as radiation (including ultraviolet light). In many instances people are exposed unknowingly to these factors and have little or no power to prevent such exposure.

To provide effective means of dealing with these problems, the Congress has enacted a number of laws under which several Federal agencies are empowered to prevent or limit human exposure to carcinogens. Annex A lists the Federal agencies primarily involved in such activities and briefly describes their authority to regulate carcinogens (excluding radiation, which is not covered in this policy statement). Because of the number of different agencies that are involved in the effort to control cancer, many people in the Administration, in Congress, and in the general public have become concerned about possible inconsistencies, duplication of effort, and lack of coordination which could make the attack on cancer less effective and more expensive than it need be.

Avoiding such problems has been one of the major priorities of this Administration. To this end, President Carter established the Regulatory Council in October 1978 to promote improved coordination of regulatory activities and to help ensure that regulatory objectives are achieved in a cost effective manner. Because of the importance of cancer in our society and the need to ensure that we control it effectively and efficiently, the President asked the Regulatory Council, as one of its first projects, to develop a statement setting forth the policies to be followed by regulatory agencies in their efforts to prevent or limit human exposure to carcinogens. This document is the product of that effort.

It in turn relies substantially upon an earlier effort undertaken by four of the regulatory agencies—the Environmental Protection Agency, Food and Drug Administration, Occupational Safety and Health Administration, and Consumer Product Safety Commission (recently joined by the Food Safety and Quality Service). Two years ago, the heads of these agencies formed the Interagency Regulatory Liaison Group (IRLG) to improve the public health through sharing of information, avoiding duplication of effort, and developing consistent regulatory policy.

Reproduced from U.S. Regulatory Council. Statement on Regulation of Chemical Carcinogens; Policy and Request for Public Comments. Federal Register, v. 44, Oct. 17, 1979 : 60037–60049.

Recognizing the importance of coordinating their regulation of cancer-causing chemicals, the agency heads asked key scientists and other staff from their agencies, the National Cancer Institute, and the National Institute of Environmental Health Sciences to prepare a document setting forth the scientific bases for making regulatory decisions on carcinogens. This group prepared a document entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" (attached as Annex B) which represents the best judgment of the participating scientists on the scientific principles applicable to identifying and evaluating substances that may pose a risk of cancer to humans.

The Regulatory Council's assignment was to consider the scientific issues addressed in the IRLC document along with the many other aspects of the government's efforts to regulate carcinogens, and to prepare a government-wide policy which reflected this Administration's actions to promote more effectively the public health without imposing unnecessary burdens upon the economy, and to eliminate potential inconsistencies and inefficiencies in the government's regulatory programs.

In carrying out this assignment the Council took account of not only the IRLC document, but many other reports and activities relating to the government's effort to control cancer. These included reports by the President's Office of Science and Technology Policy and the interagency Toxic Substances Strategy Committee, the analyses and comments relating to the Occupational Safety and Health Administration's proposed cancer policy, and the activities of the National Toxicology Program, the National Institutes of Health, and the National Cancer Advisory Board.

Although the preparation of this statement benefited from all of these efforts, it is based most substantially upon the document prepared by the IRLG. That document, attached as Annex B, should be referred to for additional information. The IRLG document has undergone scientific peer review and is currently receiving public comment; any changes made in it as a result of the review and comment process will be incorporated into this policy.

There are many important aspects of the government's efforts to reduce the seriousness of the problem of cancer in our society. These range from basic research on the biology and causes of cancer, through efforts to improve the diagnosis and treatment of the disease, to the rehabilitation of cancer victims. The focus of the Regulatory Council, however, was on issues relating to the efforts of the regulatory agencies to limit people's exposure to cancer-causing substances. Here the Council carefully reviewed the different components of the regulatory process, and the current efforts to coordinate activities in each (Annex C). As a result, it concluded that the predominant need for clarification and coordination was limited to the following four major areas of activity relating to the regulation of chemical carcinogens:

- Determining whether a chemical may cause cancer.
- Assessing the risk of cancer to humans.
- Establishing regulatory priorities.
- Undertaking regulatory activities.

These are the four areas addressed in this policy statement. An agency's actions within these areas are, of course, determined by the specific language in the applicable Federal law. However, there are many common issues which all the agencies have to deal with. This statement briefly summarizes the concepts and principles that the regulatory agencies will generally follow in each of the four areas, consistent with substantive and procedural legal constraints, in initiating regulatory action. The members of the Council do not consider this statement in any way to alter their obligations to reach decisions based upon information in the record of the particular action involved.

Determining Whether a Chemical Substance May Cause Cancer

The first step in regulating a substance as a carcinogen is to examine and evaluate the evidence that it may cause or contribute to the occurrence of human cancer. The two principal sources of such evidence are epidemiological studies involving people exposed to the substance, and testing in laboratory animals.

It is important that the regulatory agencies make such evaluations in accordance with current scientific thinking and in a consistent manner. The IRLG document "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" is a significant step in this direction. One portion of this document describes the basis for making qualitative evaluations of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal testing, along with other types of information, are used in making these evaluations.

Regulatory agencies will base their determinations of whether a substance is likely to be carcinogenic upon a rigorous evaluation of all relevant, available scientific evidence. Epidemiological studies or animal tests provide the best evidence of carcinogenicity, but other types of information can also be important. Although they cannot be adequately summarized in a few sentences it is important that there be a general understanding of several basic concepts involved in these evaluations.

Epidemiological Studies. Properly designed and conducted epidemiological studies showing a significant statistical relationship between human exposure to a substance and an increased occurrence of cancer in the exposed population are considered to provide good evidence that the substance is carcinogenic.

In the past many people argued that such studies should be considered a prerequisite to undertaking any significant regulatory action. There are, however, limitations on the usefulness of epidemiology. Everyone is exposed to many chemicals in his or her lifetime. And cancer may not occur until 30 years or more after exposure to a carcinogen. Thus, there may be a substantial delay, allowing many additional people to be exposed, before any epidemiological evidence can be obtained. Even then, it may be very difficult to associate the occurrence of cancer with exposure to specific chemicals may years previously. Epidemiological studies often cannot detect even large increases (which could involve thousands of people) in the occurrence of cancer resulting from exposure to chemicals. For these reasons:

- The failure of an epidemiological study to detect an association between the occurrence of cancer and exposure to a specific substance should not be taken to indicate necessarily that the substance is not carcinogenic.
- Because it is unacceptable to allow exposure to potential carcinogens to continue until human cancer actually occurs, regulatory agencies should not wait for epidemiological evidence before taking action to limit human exposure to chemicals considered to be carcinogenic.

Testing in Animals. Properly designed and conducted tests in laboratory animals also provide good evidence of a substance's potential human carcinogenicity. From a biological standpoint the development of cancer is similar in humans and animals, even though different species and different strains of a species may demonstrate different sensitivities to specific substances. Because we cannot test substances in humans or wait for demonstrations of carcinogenicity from epidemiological studies, Federal agencies must continue to use animal tests to identify chemical substances that may cause human cancer. In interpreting and applying the results of these tests they should use the following precepts unless there is substantial scientific or legal reason not to:

- A substance that causes cancer in animals, when tested under appropriate conditions, will be considered a potential human carcinogen.
- Animal tests provide valid information even though the dosage administered to the animals may be higher than humans are likely to experience. Animals are given relatively high doses both to increase the sensitivity of the test by maximizing the likelihood that a cancer-causing substance will actually produce cancer, and to compensate for the relatively small numbers of animals typically used in the tests. Although the likelihood of detecting a carcinogenic effect and the time between exposure to the carcinogen and the occurrence of cancer may be related to the dose level tested, the intrinsic ability of a substance to induce cancer is independent of dosage. A noncarcinogen can be toxic when administered in high doses, but it will not directly cause cancer at any dose level. In fact, the majority of chemicals tested in animals, even at high doses, has not been found to be carcinoginic.
- Evaluation of the results of animal testing is simplified when the animals are exposed by the same route by which people are or will be exposed, but the results are also relevant to human risks where exposure is by a different route. For instance, if a substance causes cancer when tested by ingestion, there is good reason to expect it to be able to cause cancer when inhaled.
- In evaluating results of animal tests, the occurrence of benign tumors in the treated animals is an indication that the substance being tested may produce malignant tumors as well. Benign tumors often are a precursor stage of malignant growths. Furthermore, virtually all extensively tested chemicals that have produced benign tumors have also produced malignant tumors.
- If a substance has been shown to be carcinogenic under the conditions of a single properly designed and conducted test, it should be considered as posing a risk of cancer to humans. Although the agencies should attempt to obtain additional data, they should not take the risk involved in waiting the two to four years required to complete an additional animal bioassay before initiating regulatory action.
- Evidence that a chemical is a carcinogen is strengthened by test results indicating carcinogenicity under two or more tests or test conditions (for example, at two or more dose levels, in both sexes, or in two or more animal strains of species). Similarly, evidence that a substance is not a carcinogen is strengthened if there is a lack of carcinogenic response in two or more properly designed and conducted tests.
- In cases where there are conflicting results from more than one properly designed and conducted test, results failing to demonstrate a carcinogenic response do not detract from the validity of results showing such a response if different species of animals were tested, and they do not ordinarily detract from such results if the same species were tested. Even known carcinogens would be expected to show no response in some tests, particularly, for instance, when relatively few animals are involved, dose levels are low, or an insensitive animal strain is used.

Other Types of Evidence. In recent years there has been encouraging progress in developing certain short-term screening tests (involving animals, mammalian cells, or micro-organisms) and in using chemical structure to predict carcinogenic potential. Such approaches may provide a substantially faster and less expensive way of obtaining evidence on a substance's potential carcinogenicity. Such evidence, although currently only considered suggestive, can properly be used for the following purposes:

- To help identify chemicals that should be more thoroughly tested.
- To help in planning priorities for regulatory actions.
- To buttress evaluations of the results of long-term testing in animals.
- To support regulatory actions dealing with groups of substances having similar chemical or biological properties.

Testing Policy: Because long-term testing in animals is so important in evaluating the cancer-causing potential of chemical substances, and because such testing is time-consuming and expensive and requires scientific expertise and specialized facilities, it is essential that it be performed as efficiently as possible. The current government policy on such testing is that:

- The primary responsibility for much of this testing, as specified in several Federal laws, lies with the firms involved in manufacturing chemical substances. Agencies having the authority to do so should ensure that any required testing is carried out properly and as expeditiously as possible.
- The Federal regulatory agencies specify the chemicals to be tested and the testing procedures to be used by industry, and ensure industry compliance with testing requirements. they also cooperate with the Federal research agencies responsible for basic research on cancer causes and treatment, to support the development and validation of new testing procedures, and to perform testing (as well as epidemiological studies) in certain circumstances, for instance, where it is not practical to rely on industry to do so or where an agency is not authorized to impose such requirements on industry.
- Although a substance may sometimes need to be tested more than once to assess its potential carcinogenicity under differing conditions, regulatory agencies will avoid, whenever possible, imposing duplicative or conflicting testing requirements. The IRLG agencies are already preparing testing guidelines to accomplish this goal.

Assessing the risk of cancer to humans

After it has been determined that a chemical substance is likely to be carcinogenic, the next step in regulatory decision-making is to assess the risk that people face of developing cancer from their exposure to the substance.

Contents of Risk Assessments. All risk assessments contain two basic components. The first is an analysis of the evidence of the carcinogenicity of the substance, and the second is an analysis of the human exposure to the substance in order to assess the health risk it may pose.

The analysis of the carcinogenicity as described in the preceding section of this statement, involves a determination of whether a substance is likely to cause cancer in humans, accompanied by a characterization of the extent and quality of the evidence supporting this determination. It may also include an analysis of the relationship between the observed carcinogenic effects and the dose levels used in animal tests or the apparent levels of exposure in epidemiological studies.

The analysis of human exposure involves at least an estimate of the size of the exposed population, and may also include such factors as exposure sources, routes, and conditions, the duration, frequency, and intensity of exposure, and the relevant characteristics (e.g., age, sex, health) of the exposed population. The agencies will use exposure measurements when they are available and reliable; otherwise, they should estimate exposure based upon reasonable assumptions and interpretations of the best data available, which may be limited to information on the manufacture, use, or environmental discharge/disposal of the chemical substance in question.

Although all risk assessments include these two basic components (analyzing the evidence of carcinogenicity and likely human exposure) the form, methodology, and elaborateness of the assessment may vary substantially. Depending upon the characteristics and extent of the available information and on the regulatory agency's specific needs, the range of approaches varies from quantitative estimates of the increased human risk of developing cancer to nonquantitative assessments of relevant epidemiological and/or testing data and evidence that people are likely to be exposed to the substance.

Risk Assessment Precepts. When undertaking risk assessments, the regulatory agencies will follow the following precepts:

- Except where a statute, as in the case with the Clean Water Act, explicitly indicates which substances are to be controlled and how, every regulatory proposal will be accompanied by some form of risk assessment which includes, at a minimum, an analysis of the evidence of the substance's carcinogenicity and a determination that people are likely to be exposed to the substance.
- The particular form and type of risk assessment undertaken will depend upon the suitability of the available information to support different types of analyses, and upon the amount of information the agency needs to support proposed regulatory actions.
- Because there is no currently recognized method for determining a no-effect level for a carcinogen in an exposed population, substances identified as carcinogens will be considered capable of causing or contributing to the development of cancer even at the lowest doses of exposure.

Where the available data are scientifically adequate to support them, quantitative risk estimates can provide useful information for proposed regulatory decisions. When they make such estimates in initiating regulatory actions, the agencies will use the procedures described in the IRLG document "Scientific Bases for the Identification of Potential Carcinogens and Estimation of Risks".

- However, quantitative risk estimates are not yet sufficiently developed to be regarded as more than rough indicators of the level of human risk. The sources of uncertainty include, for instance, the difficulties of extrapolating from one population group to another, from high doses to low doses, and from animals to man, and the impossibility of identifying or considering all the factors that affect the response of people to exposure from specific carcinogenic substances.
- In certain instances, it is impractical or unnecessary to make quantitative exposure or risk estimates. This may be true when it is impossible to predict what exposure may occur, in dealing with complex chemical mixtures of unknown or varying composition where it is not feasible to regulate each of the constituents independently, or when regulatory action is concerned with substances to which the population is exposed through a multitude of sources or products at different levels and in different ways.
- If they undertake quantitative estimates of risk, agencies will attempt to identify the range of risk that could, on the basis of available information, reasonably be associated with possible exposure to the substance. Because underestimating cancer risks could have serious public health consequences, the agencies will in particular attempt to estimate the maximum risk that could reasonably be expected.
- Because all risk assessments, whether quantitative or not, necessarily involve substantial degrees of uncertainty, they will be accompanied by statements discussing these uncertainties.

Setting priorities for regulating carcinogens

A substantial number of cancer-causing chemicals has already been identified. As other chemicals are tested, some of them also are likely to be found capable of producing cancer. In deciding which ones to regulate first, Federal agencies will generally assign higher priorities to substances for which:

- There is substantial evidence that the substance is likely to present a risk of human cancer. Epidemiological studies and/or animal testing are sources of such evidence.
- There is reason to believe that the level of human exposure and/or risk is high. Either quantitative or nonquantitative risk assessments may provide a basis for such belief.
- The exposed population is large or is of special concern, such as children.
- Regulatory action could significantly reduce the extent of intensity or human exposure.
- Regulatory action could reduce not only cancer risk but also other human health and environmental hazards.
- A substance is, or could be, available that would pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small.

The relative importance of these priority-setting criteria will necessarily vary from case to case, and in establishing their final priorities the agencies also consider:

- The requirements of applicable laws or court orders which may limit their flexibility to establish their own priorities.
- Their responsibilities for dealing with other health and environmental hazards.
- The regulatory actions being taken or planned by other agencies.

Although the agencies will continue to coordinate their regulatory actions, each agency will establish its own regulatory priorities. Specific substances usually are not equally important from the standpoint of every agency's statutory mission. As an example, one substance may provide a serious risk to workers, but very little in consumer products. Another, however, might provide a serious risk in consumer products, but present little risk to workers. The most effective public health protection would occur if the agency concerned with protecting workers gives the former a higher priority and the agency concerned with protecting consumers gives the latter a higher priority.

In general, the regulatory programs will provide the most public health protection if each agency dealing with a specific area of exposure places the highest priority on the substance which provides the greatest health risk in its area of concern. Otherwise, agencies might be regulating substances which are of relatively little importance in their area of concern, creating unnecessary regulations and costs, with little public health benefit, and putting off actions which would provide much more benefit. For these reasons, it is neither necessary nor desirable that all agencies assign the same priority to each substance.

Considering Regulatory Action

Federal laws governing the regulatory programs often prescribe the factors to be considered in choosing among regulatory options and deciding how extensive and stringent regulatory action should be. In many instances, however, regulatory agencies have latitude to interpret and apply the statutory language.

Bases for Regulatory Action. In brief, regulatory decisions generally are based upon one or some combination of the following approaches:

- *Risk.* A few statutes require agencies, when making a regulatory decision, to consider solely or primarily the risk a substance poses. If a statute requires the elimination of risk, this can be accomplished only by eliminating human exposure, because there is no known way to identify levels below which exposure to cancer-causing substances presents no risk.
- *Technical and Economic Feasibility.* Various Federal laws require that regulatory decisions be based solely or primarily upon the technical and/or economic feasibility of controlling the release of or human exposure to cancer-causing substances. The stringency sought in such feasibility-based standards is stated in the applicable law—for example, "best available technology." The statute's language determines how an agency chooses among technologies capable of reducing environmental releases of (or human exposure to) chemical substances, and whether and how it considers associated economic and other impacts in making this choice. In some instances the technological standard is also determined by requirements to achieve certain ambient exposure levels.
- *Comparing Costs and Benefits.* Various statutes permit or sometimes require regulatory agencies to ensure that the economic and social costs of regulatory action are taken into account along with the expected risk reduction. Such statutes may refer to consideration of either the costs and benefits of regulatory action or the risks a substance poses and the benefits it provides.

In some statutes, Congress, after considering the advantages and disadvantages of these different approaches, has specified that one of them be used. For instance, Congress enacted a section of the Food, Drug and Cosmetic Act that requires the Food and Drug Administration to prohibit the use of any food additive found to be carcinogenic which presumably reflected a judgment that, among other considerations, the seriousness of the risk posed by carcinogenic food additives would exceed the benefits they provide and the costs associated with not using them; while a statute enacted to regulate pesticides indicates that the agency must take into account "the economical, social, and environmental costs and benefits" associated with the pesticide's use.

The fact that cancer-causing substances enter the environment and come into contact with people by various routes means that no single regulatory approach is equally suitable for dealing with cancer-causing substances in media as different as foods, drugs, household products, workplaces, air, and drinking water. Accordingly, it is, and will continue to be, necessary for Federal regulatory agencies to make appropriate use of different regulatory approaches when making regulatory decisions.

Regulatory Principles. The agencies nevertheless will follow several common regulatory principles. These principles will ordinarily guide the agencies in initiating regulatory actions, but they will not be rigidly and uniformly applied in all cases.

- In some cases, zero risk will be an appropriate regulatory goal. It is established as such in a few national policies and statutes. It is also an appropriate goal where (e.g., in controlling specific commercial products or specific types of discharges) the economic and social costs of regulation are so slight that almost any risk would be unreasonable. This might be the case, for instance, when there are several available substitutes for the substance being regulated which are no more costly than that substance and which create no known health risks.
- Zero risk will not routinely be considered achievable. For carcinogens, existing scientific knowledge indicates that zero risk requires zero exposure. But cancer-causing substances often occur in so many different consumer products, industrial raw materials, and commerical and industrial wastes that completely eliminating exposure, even if possible to do so, could, in many cases, have unacceptable economic, social and even health impacts.
- When planning a major regulatory action, in keeping with Executive Order 12044 and other Administration regulatory reform initiatives, agencies will analyze the economic consequences of proposed regulations, will identify and consider alternatives that would achieve their health protection goals, and, to the extent consistent with applicable laws, will choose the alternative that achieves their goals with the least economic and social costs.
- In limiting a substance's use, it is sometimes appropriate to consider other products or processes which might be adopted as a substitute for the substance being regulated. In these cases, one of the factors the agencies will consider, to the extent practicable, in making their regulatory decision is the health hazards associated with such substitutes.
- To avoid conflict and duplication, if several agencies are planning to adopt regulations controlling a specific substance or problem, they will coordinate the development of their regulations. The IRLG and the Regulatory Council have already adopted mechanisms to promote such coordination.

These principles are generally in accord with the requirements of Executive Order 12044. Federal agencies have elsewhere described the specific procedures they follow in analyzing and documenting the probable environmental, public health, economic, technological, and other impacts of proposed regulations and in providing opportunities for public participation.

Further Actions. Agencies responsible for regulating carcinogens have and will continue to identify and evaluate ways of improving their regulatory programs. Among other possibilities, they have considered or will consider, when appropriate, adopting generic policies for regulating carcinogens. Some are also evaluating the advantages and disadvantages of taking interim regulatory action to reduce high exposures to cancer-causing chemical before they undertake the usually time-consuming task of establishing permanent standards and regulations.

In general, the agencies should continue their efforts to develop carcinogen regulatory programs which will effectively protect public health without imposing unnecessary or unreasonable burdens upon the economy. In this process they should ensure that their actions are consistent and coordinated, and that the public has substantial opportunity to contribute.

Annex A to Statement on Regulation of Chemical Carcinogens

Federal Agencies Having Primary Roles in the Regulation of Chemical Carcinogens

Regulatory Agencies

Consumer Product Safety Commission (CPSC)

The purpose of the Consumer Product Safety Commission is to protect the public against unreasonable health and injury risks from consumer products; to assist consumers to evaluate the comparative safety of consumer products; to develop uniform safety standards for consumer products and minimize conflicting State and local regulations, and to promote research and investigation into the causes and prevention to product-related deaths, illnesses, and injuries.

The Commission assesses the health risks associated with the use of potential carcinogens in consumer products, and has the authority to restrict or prohibit uses considered to provide an unreasonable risk. It also sponsors some research on carcinogenic substances.

The statutes defining CPSC's responsibilities for regulating carcinogens and other toxic substances include The Federal Hazardous Substances Act (1960), The Consumer Product Safety Act (1972), and The Poison Prevention Packaging Act (1970).

Environmental Protection Agency (EPA)

The purpose of the Environmental Protection Agency is to protect and enhance our environment by controlling pollution in the areas of air, noise, radiation, and toxic substances.

EPA regulates potential carcinogens under several statutes, controlling their release into the air and water, their disposal as solid or liquid wastes on land and in the ocean, their occurrence in drinking water supplies, and their use as pesticides. It also is responsible for developing national strategies for controlling the general production and use of such substances and with coordinating these activities with other agencies. EPA also conducts and sponsors research on how chemicals are transported through and modified by the environment and on the carcinogenic potential of selected substances.

The statutes defining responsibilities for regulating carcinogens and other toxic substances include The Toxic Substances Control Act (1976), The Clean Air Act (1970, amended 1977), The Clean Water Act (as amended in 1972 and 1977), The Safe Drinking Water Act (1974, amended 1977), The Federal Insecticide, Fungicide, and Rodenticide Act (1947, amended 1972, 1975, 1978), The Act of July 22, 1954 (codified as section 346(a) of the Food, Drug, and Cosmetic Act) (1954, amended 1972), and The Resource Conservation and Recovery Act (1976).

Food and Drug Administration (FDA) (U.S. Department of Health, Education and Welfare).

The purpose of the Food and Drug Administration is to protect the health of the Nation against impure and unsafe foods, drugs, cosmetics, and other potential hazards.

FDA regulates the composition, quality, and safety of foods, food additives, food contaminants, colors, human and animal drugs, medical devices, and cosmetics. It must, by law, prohibit the use of any food additive found to be a carcinogen. It also conducts and sponsors research on the carcinogenicity of food contaminants, cosmetics, and other substances, and on the development of better methods for detecting the carcinogenic potential of regulated substances. FDA also develops methods to detect the presence of these substances in consumer products and monitors them to ensure their compliance with regulations.

The statutes defining FDA's responsibilities for regulating carcinogens and other toxic substances include The Food, Drug, and Cosmetic Act (1938) with its amendments pertaining to food additives (1958), color additives (1960), new drugs (1962), and new animal drugs (1968); The Fair Packaging and Labeling Act (1976); and The Public Health Service Act (1944).

Food Safety and Quality Service (FSQS) (U.S. Department of Agriculture).

The purpose of the Food Safety and Quality Service is to provide assurance to the consumer that foods are safe, wholesome, and nutritious; that they are of good quality; and that they are informatively and honestly labeled; and to provide assistance to the marketing system through purchase of surplus food commodities and those needed in the National Food Assistance Programs.

The FSQS inspects and controls the production of meat, poultry, eggs, and dairy products to ensure, among other things, that they are not contaminated with carcinogenic substances. The statutes defining FSQS's responsibilities for regulating carcinogens and other toxic substances include The Federal Meat Inspection Act (1967), The Poultry Products Inspection Act (1957), and The Egg Products Inspection Act (1970).

Occupational Safety and Health Administration (OSHA) (U.S. Department of Labor).

The purpose of the Occupational Safety and Health Administration is to ensure, so far as possible, safe and healthful working conditions for every working man and woman in the Nation.

OSHA assesses the health risks to workers associated with the use of carcinogenic substances in the workplace, and regulates the release of and concentration of carcinogenic substances that can occur in the workplace. It also monitors job related illnesses and informs workers of the potential hazards associated with specific substances found in the workplace.

The statute defining OSHA's responsibilities for regulating carcinogen and other toxic substances is the Occupational Safety and Health Act (1970).

Materials Transportation Bureau, Federal Railroad Administration, U.S. Coast Guard (U.S. Department of Transportation).

Among its many other activities, the Department of Transportation also has the responsibility to protect the public's health and safety when hazardous materials are transported.

The Materials Transportation Bureau was established to coordinate the agency's overall responsibilities concerning the regulation of hazardous materials transportation. It has the primary responsibility for promulgating regulations for all modes of transportation and for all aspects of regulating intermodal transportation of such substances. Among their other activities, the Federal Railroad Administration implements the regulations concerning the transportation of explosives and other dangerous articles by railroads, the U.S. Coast Guard implements the regulations covering the transportation of hazardous substances by water, and the Federal Highway Administration implements them for highways.

The major statutes defining the agency's responsibilities are The Hazardous Materials Transportation Act (1970), The Federal Railroad Safety Act (1970), The Port and Waterways Safety Act (1972), and The Dangerous Cargo Act (1952).

Research Institutes

National Cancer Institute (NCI) (National Institutes of Health, U.S. Department of Health, Education and Welfare).

The purpose of the National Cancer Institute is to expand scientific knowledge on the causes, prevention, diagnosis, and treatment of cancer in order to eliminate this disease as a national health problem.

NCI conducts and sponsors research on the origin, causes, and spread of cancer and on methods for diagnosing, preventing, and treating cancer. It conducts animal tests and epidemiological studies to identify carcinogens and research directed at developing improved testing methods for identifying carcinogens. It also, through its cancer control element, applies research findings to prevent, control, and treat human cancer and to rehabilitate cancer victims.

National Institute of Environmental Health Sciences, (NIEHS) (National Institutes of Health, Department of Health, Education and Welfare).

The purpose of the National Institute of Environmental Health Sciences is to provide information on the impact of environmental factors on human health in order to aid those agencies charged with devising and instituting control or therapeutic measures.

NIEHS supports and conducts basic research focused upon the interaction between man and potentially toxic or harmful agents in his environment. This research is concentrated upon recognizing, identifying, and investigating the environmental factors that may have deleterious effects on population groups, on quantifying those efforts, and on understanding the mechanisms of action of toxic agents on biological systems.

National Institute of Occupational Safety and Health (NIOSH) (Center for Disease Control, Public Health Service, U.S. Department of Health, Education and Welfare).

The purpose of the National Institute of Occupational Safety and Health is to conduct research on and develop standards for occupational safety and health to ensure safe and healthful working conditions for all working people.

NIOSH conducts epidemiological, laboratory testing, exposure and source characterization studies on potential carcinogens found in the workplace. It also develops methods for monitoring the presence of carcinogens and for testing worker protection equipment and makes recommendations to OSHA regarding standards that should be applied to control workplace exposure and protect workers' health.

Annex B to Statement on Regulation of Chemical Carcinogens

Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks

A Report Prepared by the Interagency Regulatory Liaison Group Work Group on Risk Assessment

Annex B is filed with the Office of the Federal Register as part of the original document. See 44 FR 39858, July 6, 1979.

Annex C to Statement on Regulation of Chemical Carcinogens

Interagency Coordination Efforts Currently Relevant to the Regulation of Carcinogens

There are a number of different mechanisms in existence for the purpose of promoting coordination among the agencies. Some of these have been established legislatively, others are imposed by the President or his staff, and others have been created by the agencies themselves.

An example of legislative coordination mechanisms would include provisions in several of the health and safety statutes which require the implementing agency to consider the views of or work done by other agencies and the appropriateness and advantage of deferring to other agencies authorities to address a particular problem.[1]

Another example of legislated coordination is the National Cancer Advisory Board (NCAB) established by the National Cancer Act of 1971 (as amended) to assist the Director of the National Cancer Institute with respect to a "National Cancer Program," and to review applications for funds to conduct cancer research. The 1978 amendments to this Act included the heads of NIOSH, NIEHS, FDA, EPA, CPSC and the Secretary of Labor as *ex officio* members of this board. Other members of the board (18 are appointed by the President and 11 are *ex officio* members) represent the academic world, the public, and other Federal agencies. The NCAB not only receives and reviews reports on progress and plans from the National Cancer Institute, but has also established several subcommittees to analyze and report on particular issues of interest to the board. The National Cancer Advisory Board, composed of government and nongovernment representatives, advises NCI on policies regarding cancer research and other related issues, and thereby serves a coordinating function both within the government, and between the government and people outside government.

The Executive Office of the President, through its review and oversight functions, helps to coordinate the various cancer-related programs administratively. Such coordination particularly occurs with the budget and program reviews carried out annually by the Office of Management and Budget. The preparation of the Administration's proposed budget and the review and approval of proposed legislation both involve interagency coordination, and are necessarily fundamental steps in defining and coordinating all aspects of the government's cancer policy.

The Administration will also initiate special policy coordination reviews. An example is the Toxic Substances Strategy Committee (TSSC) which was established by the President in his 1977 Environmental Message. This committee, which is in the process of completing its work, was established (1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) "to coordinate Federal research and regulatory programs affecting them."[2] The committee is chaired by the Chairman of the Council on Environmental Quality (in the Executive Office of the President), and includes 17 agencies involved in the effort to control toxic substances. The TSSC adopted a work plan and established work groups to deal with many of the issues involved in regulating carcinogens.[3] The reports of the work groups were summarized in the committee's final report which has been released in draft form for public comment.[4]

A third example of such coordination efforts is the Regulatory Council established by President Carter in October 1978. This council, composed of 35 departments and agencies with significant regulatory responsibilities, was created to coordinate the activities of the regulatory agencies and to assist them in implementing their regulatory programs in a consistent and cost-effective manner. Nineteen independent regulatory agencies also contribute to the council's activities in various ways. The first responsibility of the council was to prepare a "regulatory calendar" which summarized the important Federal regulations under development.[5] The council will also undertake various other policy and procedural coordination efforts related to the regulation of carcinogens.

An example of coordination efforts instituted by the agencies themselves is the Interagency Regulatory Liaison Group (IRLG). This is perhaps the most ambitious of such coordinating efforts. It was formed in 1977 by four agencies—the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration, and was expanded in December, 1978, to include the Food Safety and Quality Service of the Department of Agriculture. All five agencies are responsible for regulating hazardous substances—protecting people from excessive exposure to such substances in their food, drugs, consumer goods, workplace, and in the air and water. The IRLG established a series of work groups and task forces to deal with many of the regulatory and research issues which affect the agencies, both at headquarters and in each of the 10 Federal regions. These groups have been carrying out projects which are directly related to ensuring better coordination of carcinogen regulatory programs.

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[1] For example, section 9 of the Toxic Substances Control Act and section 28 of the Consumer Product Safety Act.

[2] The President's Message to the Congress on the Environment, May 23, 1977, Section I.

[3] (42 FR 37[illegible]).

[4] (44 FR 48134, Part IV).

[5] The first calendar was published on Wednesday, February 28, 1979 (44 FR 11[illegible]).

A closely related effort, the National Toxicology Program (NTP), was established in November, 1978, by the Department of Health, Education, and Welfare to coordinate the activities of HEW's several institutes and bureaus devoted to toxicological research and testing. The broad goal of this program is to strengthen HEW's activities in the testing of chemicals of public health concern, as well as in the development and validation of new and better integrated test methods. At present the NTP is comprised of the relevant activities of the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the Center for Disease Control/National Institute for Occupational Safety and Health (NIOSH), and the National Institute of Environmental Health Sciences (NIEHS). In order to ensure that these activities within HEW are coordinated with the needs and activities of the regulatory agencies, the original four IRLG agencies are members of the program's executive committee.

The coordinating programs described above are some of the more important and broader ranging efforts. However, a number of less extensive coordinating mechanisms have been established to deal with specific issues. These, and the particular activities of the broader programs, are described in the remainder of this annex.

Identifying Carcinogens

Much of the effort to coordinate carcinogen policies has focused on the scientific issues involved in testing carcinogenic substances and assessing carcinogenic risks. As a result, this is the general area in which most progress has already been made. The IRLG has focused many of its activities in this area and the National Toxicology Program was established to bring about further coordination. In addition, there have been a number of administrative and legislative efforts at coordination that have focused in this area.

Research

A number of different government agencies have developed significant research programs to gain a better understanding of carcinogens and the way in which they affect humans. The largest programs are sponsored by the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute of Occupational safety and Health, the Environmental Protection Agency, the Food and Drug Administration, the Department of Energy, the Department of Defense, the Department of Commerce, and the Department of Agriculture.

According to one tabulation, these agencies spent a total of approximately $400 million dollars in FY 1977 in research related to toxic substances, a large proportion of which was focused on the problem of cancer and carcinogens.*

These research programs tended to develop in a largely uncoordinated fashion, but during the past year there have been several major efforts to gain a better understanding and improve the coordination of different agencies' research programs. The first of these was the IRLG Research Planning Work Group. This group tabulated all the toxics research being sponsored by the four IRLG agencies plus three research institutes (NCI, NIEHS, and NIOSH) and analyzed this information to try to identify areas of overlap or particular gaps in the research programs. They did not isolate cancer-related research but analyzed it along with their other toxics research. They discovered few instances of possible research overlaps, but did identify some potentially serious research gaps.

A similar effort was initiated by the Toxic Substances Strategy Committee covering more agencies than the seven included in the IRLG's effort. This analysis was based upon the information collected by the IRLG Research Planning Work Group, the Smithsonian Institution's Scientific Information Exchange System, and special submissions by individual agencies. Again, there was no specific focus on cancer-related research, although it was included with the other toxics research. Like the IRLG effort they found little evidence of duplication, but some possibly significant gaps.

Concern about the budgetary coordination of toxics-related research led the Office of Management and Budget to initiate a cross-agency "Zero-Based Budget" (ZBB) exercise for the 1980 budget year. This exercise included the same agencies in the IRLG effort (the four IRLG agencies, NCI, NIEHS, and NIOSH). For this exercise each agency divided its research into "decision units" which were ranked jointly by all the agencies according to commonly agreed upon criteria relating primarily to the quality and importance of the research. Again, there was not particular focus on cancer-related research, and no effort was made to obtain a specific understanding of what was being done in this subject area.

The fourth effort, the National Toxicology Program, is focusing more on developing an ongoing management system for planning and coordinating research done under different auspices within HEW. This program was given authority to plan use of part of the research budget for four agencies—NCI, NIEHS, NIOSH, and FDA. The program does not cover all of the cancer-related research, but does include most of that testing within HEW directly relevant to the identification of carcinogens. In order to ensure that the HEW research plans are coordinated with the research and information needs of other agencies, three of these agencies (EPA, OSHA, and CPSC) are members of the Executive committee which reviews the program plans.

The National Toxicology Program is related to a broader Department of Health, Education and Welfare coordination effort, the Committee to Coordinate Toxicology and Related Programs. This committee provides advice to the department on toxicological activities and serves to coordinate the exchange of information and the sharing of resources among agencies in the department. Although established within HEW, it includes liaison members from most other Federal agencies having significant interests in toxicology, and thus serves as a focus for more general information exchange and coordination.

Two other research planning, advising, and coordinating efforts also deserve mention. These include the National Cancer Advisory Board and the NCI Clearinghouse for Environmental Carcinogens. Each of these efforts is primarily concerned with the programs and activities of the National Cancer Institute. However, each accomplishes some important coordination among agencies. Their membership includes representatives from other agencies and the public. The National Cancer Advisory Board reviews all research applications submitted to the National Cancer Institute, and, in addition has a subgroup focusing upon environmental carcinogenesis. The NCI clearinghouse, which includes even broader representation from other agencies, is concerned with planning and advising on test methods and priorities and with evaluating the results of NCI's testing and associated risk assessments.

Testing Priorities

In the past, each of the agencies doing carcinogenesis testing tended to set its own testing standards and establish its own priorities.

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*Toxic substances Strategy Committee, "Toxic Substances: A Review of Federal Research, Development, Testing and Monitoring Activities," August 1978.

Some consistency in priority setting was accomplished through various advisory committees, of which NCI's Clearinghouse on Environmental Carcinogenesis was perhaps the most important. Although NCI and other testing agencies did attempt to respond to regulatory needs when they were expressed, the regulatory agencies often did not have strong inputs to those committees.

The creation of the National Toxicology Program has established a more vigorous forum for coordinating testing priorities. This program is developing criteria for setting testing priorities which reflect the needs of both the regulatory agencies and the research institutes. The regulatory agencies, represented on the program's Executive Committee, will also have a stronger role in selecting the specific substances tested for all of the HEW testing programs covered by the NTP.

Another major program established to coordinate testing is the Interagency Toxic Substances Testing Committee. This committee was established by section 4(e) of the Toxic Substances Control Act of 1977, and includes members from eight agencies involved in regulating toxic substances. Its role is to review current knowledge of the potential toxic effects of different substances, and recommend to EPA which of these substances should receive highest priority for testing. EPA then reviews these recommendations in terms of the priorities it will establish for tests to be conducted by industry under section 4 of the Act.

The National Toxicology Program and the Interagency Toxic Substances Testing Committee substantially improve the amount of coordination occurring on setting testing priorities. The National Toxicology Program will serve to coordinate testing priorities among the research agencies and the regulatory agencies, and the testing committee will serve to coordinate priorities between the government and private sector. Coordination between these two efforts results from having the same agencies represented on both.

Conduct of Studies

Typically, when laboratory testing is as diffused and is changing as rapidly as it is in the case of cancer research, a number of different experimental methods tend to come into use. To a large extent this is desirable, for it allows for development of new equipment and techniques, and often results in discovery of more efficient and accurate procedures. However, for the purpose of making regulatory decisions, the agencies must have confidence in the quality of the testing, and in the consistency of test results.

Efforts to promote such quality and consistency can take several forms. The first stage is usually the development of suggested analytical methods for use within an agency. Some of these will be adopted by other agencies as well. For instance, the National Cancer Institute has prepared manuals containing recommended testing methods for determining carcinogenesis. The National Academy of Sciences, the World Health Organization, FDA, and EPA have also prepared such manuals.

As more experience is gained with the different methods, the agencies begin to agree on what the preferred methods are. In the second stage of coordination, the different agencies adopt consistent methods. Thus, HEW prepared regulations defining Good Laboratory Practices, and during the past year these have also been accepted by EPA, CPSC, FDA, and OSHA. This has represented a significant step forward in consistency and quality control.

An associated problem is being addressed by the IRLC Work Group on Testing Standards and Guidelines. This work group is addressing the problem that would be created if the different agencies where to require slightly different testing procedures, all of which might be equally acceptable from the standpoint of quality control, to be used in conjunction with their specific regulatory programs. These differences can cause confusion and unnecessary costs by requiring a firm to undertake somewhat different tests on the same substance when trying to satisfy different regulatory requirements. The IRLC Testing Standards and Guidelines Work Group is attempting to avoid this problem by developing one set of testing standards that will be accepted by all the IRLC agencies.

The IRLC Epidemiology Work Group is attempting to accomplish some of the same improvements with respect to epidemiological studies. However, this group is focusing more on defining the minimal characteristics of epidemiological studies than in defining study protocols similar to those being developed by the Testing Standards and Guidelines Work Group.

Similar coordination of testing methods is occurring in the international context through the Organizations for Economic Development and, to a lesser extent, United Nations' associated organizations such as the World Health Organization and the Food and Agriculture Organization.

Identifying Carcinogens

With the profusion of different testing and regulatory programs, there has been some concern that different agencies will make inconsistent assessments of the potential carcinogenicity of a particular substance. This concern has created a substantial interest during the past 2 years in developing procedures for ensuring that these qualitative assessments of risks are consistent.

One of the more ambitious of these efforts was the report prepared by the IRLC Risk Assessment Work Group entitled "Scientific Bases for the Identification of Potential Carcinogens and the Estimation of Risks."[7] This document represents the judgment of the agency scientists on the scientific concepts and methods used to identify and evaluate substances that pose a risk of cancer to humans. The document describes the bases for making a qualitative evaluation of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.

Several other efforts in the government have also addressed this issue. The National Cancer Advisory Board's Committee on Environmental Carcinogenesis is preparing a document which is similar to that prepared by the IRLC. The Office of Science and Technology Policy, in the Executive Office of the President, has also prepared a similar document.

Another step to promote consistency is the effort by the National Cancer Institute to disseminate the results of its carcinogen assessments. This is done through the Clearinghouse on Environmental Carcinogenesis and via an annual report on Carcinogens NCF is required to make to Congress under a recent amendment to the National Cancer Act.[8]

Assessing Human Risk

Most of the government's attention on issues relating to the assessment of human risk has been focused on the appropriateness and methodologies for making quantitative risk estimates.

A number of different estimation techniques have been proposed and used without general agreement about their accuracy and reliability. Because of the substantial uncertainties involved, it is probably not possible to determine whether a specific estimation technique is correct. It is nevertheless desirable for all agencies using quantitative estimates in their regulatory programs to make such estimates consistently.

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[7] (44 FR. [illegible]) and *Journal of the National Cancer Institute*, Vol. 63, No. 1 (July, 1979), pp. 241–[illegible]

[8] Pub. L. 95–622, Title II, Part E, section [illegible]

A major purpose of the IRLG Risk Assessment Work Group was to provide a framework for this consistency. Their report ("Scientific Bases for the Identification of Potential Carcinogens and Estimation of Risks") describes some methods that are used in making quantitative estimates of the Carcinogenic risks posed by a substance if such risk estimates are appropriate or required. The report discusses the various quantitative estimation techniques currently being used, the various problems associated with such estimation techniques, and recommends that the agencies include the results from one particular technique when undertaking quantitative risk estimations. This document should serve both to insure that the agencies interpret data consistently and to reduce the public's uncertainty about the scientific and policy judgments that the agencies make in their interpretations.

Regulatory Policies

Until recently, most efforts to coordinate agency actions in regulating carcinogens focused upon the scientific aspects of the regulatory programs—the testing of substances, the assessment of hazards, the estimation of risks. As these become better coordinated, the emphasis is shifting—particularly with the establishment of the IRLG and The Regulatory Council—to coordinating government intervention as well. These efforts are dealing with issues such as setting regulatory priorities, agreeing upon what analyses ought to be undertaken to support regulatory decisions, coordinating specific regulatory actions, and coordinating compliance monitoring and enforcement.

Regulatory Priorities

The IRLG regulatory Development Work Group is responsible for the major efforts to coordinate regulatory priorities among agencies. It has set up a process whereby each agency is notified immediately as soon as one of the agencies begins to consider regulating a particular substance. With this arrangement the agencies are aware of one another's priorities and can reevaluate their own priorities in view of other agency plans.

Decision Analyses

The major coordination on decision analyses has resulted from Executive Order 12044 issued by President Carter[9] and The National Environmental Policy Act.

The National Environmental Policy Act requires each agency to analyse the environmental implications of those actions which may have a significant impact upon the human environment. The Council on Environmental Quality implements these provisions and has issued regulations governing the preparation and processing of environmental impact statements.[10] However, there is some variation among agencies regarding how and when they undertake environmental impact assessments related to regulatory activities.

Executive Order 12044 applies to all regulations which potentially have a major economic impact issue by agencies within the Executive Branch. It requires agencies proposing these regulations to undertake regulatory analyses which are published for review and comment. The Council on Wage and Price Stability and the Office of Management and Budget have prepared guidelines regarding the content of these analyses and the way in which they should be done.[11]

Selected regulatory analyses are also reviewed by the Regulatory Analysis Review Group (RARG). This group is chaired by the Chairman of the Council of Economic Advisors and is made up of representatives from the Office of Management and Budget and the principal Executive Branch economic and regulatory agencies. RARG reviews up to 20 regulations a year (not more than 4 from any one agency) which it believes may have a significant impact upon the economy. The implementation of Executive Order 12044 has resulted in substantial consistency with respect to the issues of when economic analyses will be conducted and what they should contain.

The IRLG Regulatory Development Work Group is also concerned with what analyses are done and how they are coordinated among the IRLG agencies. The IRLG also has a group of Senior Economists to coordinate the economic analyses carried out by different agencies and to develop common analytical tools and data bases that could be used in these analyses.

Regulatory Actions

The type of actions that regulatory agencies can take and the considerations and principles that are to be taken into account in deciding upon these actions are largely specified by Congress in the statutes establishing the various regulatory programs. However, there are several major efforts to coordinate the agencies' actions within these statutory constraints.

The IRLG agencies are attempting to coordinate their regulatory actions through the Regulatory Development Work Group. This work group has identified the hazardous substances which two or more of the IRLG agencies are currently considering regulating. For each of these substances the work group has established a special subgroup composed of key officials from the relevant agencies. These subgroups have the responsibility for coordinating the actitities of the various agencies, ensuring that they are consistent with one another and informing the public on what each of the agencies is doing. As part of this effort they have prepared a document entitled *Hazardous Substances* which lists 24 substances; summarizes what is known about their health effects, production, and use; lists the regulatory authorities under which action is being taken or considered; indicates certain regulatory issues that have arisen; and sets forth the agencies' proposed schedule of regulatory activities.[12] The information in this document is being updated semi-annually by an IRLG publication entitled *Regulatory Reporter.*[13]

The Regulatory Council's "regulatory calendar" should also serve as an important coordinating mechanism.[14] The calendar contains a listing of all the important rules and regulations that the agencies are working on, the benefits and costs anticipated to result from the agency's regulatory action, and the alternative actions being considered. The preparation and public release of this calendar should serve to increase the consistency of agency interventions. In addition, the staff of The Regulatory Council will examine the submissions to identify possible conflicts, inconsistencies, or instances of overlap.

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[9] Executive Order 12044, "Improving Government Regulations," issued by the President on March 23, 1978 (42 FR 38780).

[10] 43 FR 55978 (November 29, 1978, Pt. 6).

[11] Memorandum from Wayne G. Granquist, Associate Director, Management and Regulatory Policy, Office of Management and Budget to the "Heads of Departments and Agencies," Subject: Guidance for Regulatory Analysis, dated November [illegible] 1978.

[12] Interagency Regulatory Liaison Group, *Hazardous Substances* (Washington, D.C., U.S. Government Printing Office, December 1, 1978).

[13] Interagency Regulatory Liaison Group, *Regulatory Reporter*, Vol. 1, Issue 1, published June, 1979 (Washington, D.C., U.S. Government Printing Office).

[14] The first calendar was published in the *Federal Register* on February 28, 1979, a 44 *Federal Register* [illegible]

Executive Order 12044 (and NEPA, where applicable) also requires agencies to analyse proposed interventions and the reasonable alternative means of intervention in the economic (or environmental) impact statements they are required to prepare. The economic impact statements are reviewed by the Council on Wage and Price Stability which attempts, among other things, to identify any inconsistencies among the agencies. Where potentially serious inconsistencies appear, the proposed intervention may be referred to the Regulatory Analysis Review Group for more intensive consideration.

The potential for coordination and the benefits that can result if the agencies do work closely together were clearly demonstrated in the regulation of chlorofluorocarbons. Chlorofluorocarbons were at one time used extensively as propellants in aerosol sprays, among other uses. They were found, however, to be causing a potentially serious depletion of ozone in the atmosphere.

Various scientific studies demonstrated that such depletion could have very serious long-range impacts on health and the environment. Three agencies, EPA, CPSC, and FDA, had partial jurisdiction. When it became evident that there was a potentially serious problem, these agencies met together to consider possible regulatory responses. As a result, they developed a joint regulatory approach that embodied agreement on the actions that each of the agencies would take and the timing of these actions. This arrangement resulted in one of the agencies (CPSC) agreeing to take no action at all because it would have done little more than duplicate what the regulations of the other two agenices would accomplish. This cooperation enabled the three agencies to announce jointly what each of them would be doing and when, eliminating any uncertainty about the specific interventions that were planned. The agencies also jointly undertook to sponsor additional research on the problem to determine whether further actions with respect to nonaerosol uses of clorofluorocarbons were needed and how any such intervention could most efficiently occur.

Monitoring

Ambient and compliance monitoring are important aspects of any regulatory program. Ambient monitoring involves identifying the existence of potential carcinogens in places—e. g., the air, food products, consumer products, the workplace—where people may be exposed to them. Compliance monitoring involves determining whether sources of these contaminants are complying with regulations to control people's exposure to such substances.

In the past, the main coordination of monitoring has resulted from the regulatory agencies using data collected by other data-collecting agencies such as HEW's Center for Health Statistics. Recently, the coordination of ambient monitoring has been looked at in greater detail by an interagency committee established by the Council on Environmental Quality to review environmental data and monitoring, by the Interagency Toxic Substances Data Committee, by the IRLC Information Exchange Work Group, and by the Office of Management and Budget. Various efforts have also been undertaken to coordinate compliance monitoring through the IRLC Compliance and Enforcement Work Group and various regional IRLC organizations.

The President established the CEQ Interagency Task Force on Environmental Data and Monitoring in his Environmental Message of May, 1977.[10] This task force has undertaken an extensive review of the government's efforts to monitor air pollutants, water pollutants, and other environmental characteristics. However, it has deferred consideration of carcinogen and toxics monitoring to the Interagency Toxic Substances Data Committee.

The Interagency Toxic Substances Data Committee was established by section 4(e) of The Toxic Substances Control Act. Its purpose is to facilitate the exchange of information on toxic substances among agencies. Although the focus is on information exchange, it must also consider who should collect the information and how they should collect it. The issues being addressed by this interagency committee are closely coordinated with those being addressed by the IRLC Information Exchange Work Group, which serves a similar role among the IRLC agencies. However, neither of these efforts has yet led to an intensive effort to improve the coordination of ambient monitoring activities by the different agencies.

The coordination carried out by the Office of Management and Budget occurs primarily with respect to the budget submissions of the individual agencies and to the clearance of the forms which will be used to collect the information. The coordination of data collection efforts is further emphasized in The Regulatory Reform Act of 1979 submitted to the Congress by the President in March, 1979.

There is, however, a significant increase in the coordination of compliance monitoring by the agencies. In the agencies' regional offices, inspectors from each agency are being educated about the programs of the other agencies. A process for referring possible violations of another agency's regulations to that agency has also been instituted. The IRLC Compliance and Enforcement Work Group has developed the educational materials and the forms being used in this effort. This work group is also exploring the possibility of such further coordination as joint inspections (where inspectors from different agencies inspect a site jointly) and cross-over inspections (where the inspectors from one agency inspect for other agencies as well as their own).

An important contribution to such coordination may result from a demonstration project in New Jersey conducted by the Environmental Protection Agency in association with the IRLC Information Exchange Work Group. A serious hurdle to better coordination has been that the different agencies, and often different programs within the same agency, do not use the same means for identifying individual facilities being controlled. The New Jersey project is exploring the feasibility of developing a "common code" system of identifying facilities. If such codes were used to identify facilities and sites, one could quickly identify how each agency is involved with any particular facility or site, when any agency last inspected the facility, whether any and what type of violations have been found, etc.

Enforcement

The primary coordination of enforcement policies is occurring through the IRLC Compliance and Enforcement Work Group and IRLC cooperation among the regional offices. In addition to the training of inspectors and the referral of violations, there has been increased mutual support of enforcement actions through the sharing of laboratory facilities, information, and expert witnesses among agencies, and by the agencies undertaking special investigations for one another.

Agency coordination is also important in responding to emergency episodes, such as spills or plant accidents, involving the release of toxic chemicals. The Toxic Substances Strategy Committee established a special subcommittee to address this problem. It has concentrated upon improving the response capacity at the State and local levels, better organizing EPA's response system, and achieving better coordination between EPA, the Department of Transportation, and the private sector. In addition, the IRLG agencies have developed, at both regional and headquarters levels, emergency notification schemes and emergency response plans to deal with such episodes. These are currently being integrated with the national response system established by The Clean Water Act (involving the Council on Environmental Quality, the Department of Transportation, and EPA) to respond to oil and hazardous substances spills.

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[10] The President's Message to Congress on the Environment, May 23, 1977.

Conclusion

This appendix describes some of the ongoing coordination efforts which are most relevant to the regulation of carcinogens. Additional efforts are also occurring in areas less directly related. Further information about the activities of the major coordinating efforts can be obtained by contacting the following:

Interagency Regulatory Liaison Group, 1111 18th Street, NW. (Room 500), Washington, D.C. 20207

The Regulatory Council, New Executive Office Building, 726 Jackson Place, NW., Washington, D.C. 20460

National Cancer Advisory Board, National Cancer Institute, Public Health Service, U.S. Department of Health, Education, and Welfare, 900 Rockville Pike, Bethesda, Maryland 20014

National Toxicology Program, National Institute of Environmental Health Sciences, Public Health Service, Department of Health, Education, and Welfare, Bethesda, Maryland 20014

Table 1—Interagency Coordination Efforts

Overall Coordination Efforts

- Office of Management and Budget:
  - Budget preparation
  - Legislative clearance
- Toxic Substances Strategy Committee (TSCC)
- Regulatory Council
- Interagency Regulatory Liaison Group (IRLG)
- Committee to Coordinate Toxicology and Related Programs (HEW)
- National Toxicology Program (NTP)
- National Cancer Advisory Board

Identifying Carcinogens

- Research:
  - IRLG Research Planning Work Group
  - TSSC
  - Interagency Toxic Substances Zero Based Budget Analysis
  - NTP
  - National Cancer Advisory Board
  - National Cancer Institute Clearinghouse for Environmental Carcinogens
  - IRLC Preventive Health Initiative
  - CCTRP
  - Interagency Collaborative Group on Environmental Carcinogens
- Testing Priorities:
  - NTP
  - Interagency Toxic Substances Testing Committee
  - NCI Chemical Selection Committee
- Conduct of Studies:
  - Manuals of recommended testing procedures (e.g., NCI)
  - Good Laboratory Practices
  - IRLG Testing Standards and Guidelines Work Group
  - IRLG Epidemiology Work Group
  - Various international efforts
- Assessing Human Risk:
  - IRLG Risk Assessment Work Group
  - Office of Science and Technology Policy
  - NCI Clearinghouse on Environmental Carcinogens
  - Annual Report of NCI
  - National Cancer Advisory Board Committee on Environmental Carcinogens

Regulatory Policies

- Regulatory Priorities:
  - IRLG Regulatory Development Work Group
  - TSSC
- Decision Analyses:
  - National Environmental Policy Act
  - Executive Order 12044
  - Regulatory Analysis Review Group (RARG)
- Regulatory Actions:
  - IRLG Regulatory Development Group
  - Regulatory Council
  - Executive Order 12044
- Monitoring:
  - Control Data Collection Agencies, Center for Health Statistics
  - Interagency Toxic Substances Data Committee
  - IRLG Information Exchange Work Group
  - Office of Management and Budget
    - Survey clearance functions
    - Budget preparation
  - IRLG Compliance and Enforcement Work Group
    - IRLG regional activities
- Enforcement:
  - IRLG Compliance and Enforcement Work Group
  - IRLG regional activities
  - TSSC
  - National Response System

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AIHC AMERICAN INDUSTRIAL HEALTH COUNCIL
1612 K STREET, N.W., SUITE 308, WASHINGTON, D.C. • (202) 659-0060

November 15, 1979

Toward a Sound National Cancer Policy

AIHC Comments on the Statement of the Regulatory Council Entitled "Regulation of Chemical Carcinogens"

The purpose of this memorandum is to provide suggestions of the American Industrial Health Council (AIHC) for the improvement of the statement of the Regulatory Council entitled "Regulation of Chemical Carcinogens" released September 28, 1979 (44 Fed. Reg. 60038). We do not believe that line by line comment on the statement would be helpful. Our purpose is to identify those areas where we believe the Council's statement could be materially strengthened so that the statement embodies the latest scientific expression of the state-of-the-art in risk identification and estimation. In the letter which this memorandum accompanies, AIHC has made recommendations for the next steps to be taken to develop a sound national cancer policy. These recommendations will also be discussed briefly in this memorandum.

AIHC was formed to coordinate the scientific and administrative resources of its 120 member companies and 60 participating associations to address the problem of regulation of substances which present a chronic health hazard.

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A prime objective is to mobilize the scientific talent, industrial experience and administrative expertise of its members to assist government agencies in the development of sound carcinogen control. A list of AIHC members is attached.

I. Scientific Risk Assessment Should be Improved and its Use Extended

Within the specific focus of regulation of particular substances addressed in the Regulatory Council statement, there is an urgent need to develop policies which will provide a basis to evaluate for regulatory consideration the rapidly increasing number of substances for which some evidence of possible carcinogenicity will be developed from the greatly expanded government and private research programs and the expanding array of testing methodologies.

Mr. Costle's public statement in connection with the release of the Regulatory Council's statement tended to obscure rather than address the problem. To substantiate the assertion that "everything does not cause cancer", he stated that only 500 out of 7,000 chemicals tested have been shown to cause cancer. However, as he noted, the quality of the studies on 7,000 substances varied widely. He referred also to a 1969 study done by Litton for NCI on 120 pesticides where 11 were found carcinogenic, but the protocols followed would probably not be used today.

The fact that nearly one half of the substances tested in the NCI bioassay program provided some evidence of carcinogenicity in animal tests is probably a more accurate forecast of the outcome of the enormously increased public and private testing programs. The need for good scientific tools to discriminate and evaluate different risks is important in fields other than industrial chemicals. This conclusion is confirmed by the recent statement of the Food and Drug Administration that "many, perhaps most, foods in a supermarket" may contain "an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) . . . ." (44 Fed. Reg. 59513, October 16, 1979). The important point is that improved procedures are necessary to evaluate carcinogenic risk and to regulate those substances that are carcinogenic according to the risk they present.

In these circumstances it is vitally urgent that the government develop the tools to assess the risk presented by this vast myriad of substances which will be implicated by some evidence. Substances vary greatly in carcinogenic potency. The Interagency Regulatory Liaison Group Report (IRLG) stated that the range in variation in potency is more than a millionfold. (44 Fed. Reg. 39875). The range of hazard from these substances will be much greater because of differences in exposure levels.

It is indispensible that the government develop the means to select which substances in this large and growing group should have regulatory attention. Scientific identification and quantitative estimation of the risk are essential to enable sound decisions to be made. The IRLG Report is a welcome beginning in the development of objective scientific risk assessment. AIHC has commented on the IRLG Report in detail. A summary of the AIHC comments is attached to this memo. The full text of the AIHC comments is being submitted to the Regulatory Council.

The endorsement of the IRLG Report by the Regulatory Council is welcome, but we are disappointed in three respects.

(1) The summary/primer style description of the "evidence" of carcinogenicity results is a distortion of complex, qualified scientific principles.

(2) The Regulatory Council does not encourage full use of risk estimation.

(3) The Council's statement repeats points from the IRLG Report which public input will indicate should be corrected, modified or qualified.

(1) The statement which appears to be a key to the Regulatory Council's policy that "the intrinsic ability of a substance to induce cancer is independent of dosage" (44 Fed. Reg. 60040) is a misleading overstatement. Where the mechanism by which a substance acts is epigenetic (e.g. tissue damage) a threshold is likely. (See AIHC comments on the IRLG Report at III-12 and III-13.) Moreover this statement overlooks the significant role of hormones and bionutrients

such as Vitamin A, cobalt, chromium, nickel, selenium, etc., which are essential to life but may cause cancer at high doses.

The statement points out that evidence that a substance is carcinogenic is strengthened by test results indicating carcinogenicity under two or more test conditions. This might be correct if the statement referred, as it does in the next sentence, to "two or more properly designed and conducted tests." (44 Fed. Reg. 60040). It is clear, however, that the author of the statement intended no such meaning because the parenthetical clause, "two or more tests or test conditions" is defined to mean "at two or more dosage levels, in both sexes, or in two or more animal strains or species." To suggest that one study with two doses is the equivalent of two tests or that one study with both sexes is the equivalent of two studies goes beyond any assertions in the IRLG Report or elsewhere.

Another example where the Regulatory Council's summary overstates the value of evidence of carcinogenicity is with reference to short term tests. (44 Fed. Reg. 60040). None of these tests has been validated so that different laboratories following the same protocol consistently get the same result. To suggest that results of such tests, without specifying a properly validated battery or the design and conduct of the tests, can be used to support "regulatory actions dealing with groups of substances having similar chemical or biological properties" elevates improperly the test results which the statement acknowledges are only "suggestive." Combining the short term tests with another criterion, similarity in structure, which also is at best only suggestive, to support regulatory action goes beyond any proposal by the IRLG or any agency except the proposed CPSC policy (43 Fed. Reg. 25658) which has been withdrawn. (44 Fed. Reg. 23821). The limitations of short term test data is discussed in greater detail in the AIHC comments on the IRLG Report at II-10 to II-16.

(2) The statement fails to provide leadership for the improvement and wider regulatory use of quantitative risk assessment. The "minimum" risk assessment called for by the statement consists merely of qualitative identification of potential carcinogenicity of a substance and a determination that people are likely to be exposed. Other significant factors necessary to properly quantify human exposure "may also" be included in the risk assessment but unfortunately are not required elements of the Regulatory Council's recommendations.

Such an inadequate non-quantitative risk assessment provides no guidance whatsoever to the nature of the risk, provides no basis for assessing alternatives and will not enable the agency or the public to determine whether the health benefits from the regulation bear a reasonable or, indeed, any relationship to the cost.

The Regulatory Council should underline the importance of a full quantitative risk estimation to sound regulation.

(3) The Council includes a number of statements from the IRLG Report which AIHC believes public comment will show should be corrected, qualified or modified. This includes

statements which fail to give appropriate weight and encouragement to the collection of human data; overemphasize the significance of tests at maximum tolerated dose and positive animal test results; fail to emphasize the importance of comparative metabolism; give undue weight to benign tumors and fail to give due weight to differences in route of exposure; fail to urge selection of all methodologies and models on the basis of scientific validity rather than conservatism; and others.

Three major statements on cancer have been published by the government in quick succession without evaluation of public input: The IRLG Report; the draft Report of the Toxic Substances Strategy Committees (TSSC); and the Regulatory Council statement. The comment period was extended for the IRLG Report which forms the basis of much that is contained in the TSSC draft report and the Regulatory Council statement. Public comments have not been evaluated. While the Regulatory Council promised to include modifications of the IRLG Report in its statement, it is very unfortunate that a government document as important as the Regulatory Council statement should be issued before public comments were evaluated.

AIHC's comments on these and other points are summarized in the attachment to this memo and are developed in detail in the AIHC comments on the IRLG Report.

II. The Scientific Basis for Risk Estimation Should be Strengthened

Much of the statement by the Regulatory Council either characterizes or refers to the scientific input to the regulatory process. We find it unusual, therefore, that the Regulatory Council gave no guidance to the agencies to assure that regulation is based on the best available science.

Four principles should be enunciated by the Regulatory Council to provide direction to the agencies in making scientific risk estimations which are an essential part of a regulatory analysis.

> First, the scientific functions of qualitative risk identification and quantitative risk estimation, which the President's Office of Science and Technology Policy (OSTP) called "Stage I" in the regulatory process, should be separated from the regulatory function which OSTP calls "Stage II", where societal values (risks, benefits, costs, safety factors etc.) can be expressly considered by the regulator in deciding what action to take for risk avoidance;(1)
>
> Second, the scientific risk assessment should have the objective of presenting to the regulator (and to the public) the most objective unbiased assessment based on scientific evaluation of all the facts. To accomplish that objective, the scientific analysis must not be constrained or biased in some undisclosed way by "conservative" assumptions or models. Individual scientists may be conser-

vative or liberal but science must be objective.

Third, the agencies should reward good science by recognizing the significance of new data and new methodologies. The agencies should be open-minded to new data, particularly as it relates to the validity of the extrapolation of animal data to man.

Fourth, the Regulatory Council should ensure that the agencies establish consistent minimum standards of quality for acceptable data - scientific peer review, etc.

The Council should make the upgrading of the science upon which the regulatory agencies must rely an essential objective of its policy statement. AIHC gave this objective prime priority by its recommendation that an independent science panel of the highest qualifications be created to make the scientific risk evaluation; this would ensure the best objective science as a basis for regulatory decisions. The Council should also take leadership in encouraging the improvement in scientific risk estimation by the regulatory agencies.

III. The Regulatory Council Should Provide Guidance to Assure that Regulatory Objectives are Achieved in a Cost Effective Manner

The cost of regulation has become a matter of urgent national concern. A recent study prepared for the Joint Economic

Committee of the Congress estimated regulatory costs for 1979 to be over $100 billion.(2) The $97.9 billion cost of compliance component in that total is, the study states, "substantially underestimated."

These cost considerations highlight the Council's objective to help ensure that regulations are achieved in a cost effective manner. The Council's statement should be amended to provide guidance to the agencies in the following important respects.

First, as we have pointed out earlier, supra p.6, the approval by the Council of a "minimum" risk estimation consisting only of qualitative identification of a carcinogen and an observation that people are likely to be exposed provides no guidance to the regulator whether the benefits of the proposed regulation bear a reasonable relation to the cost. For a regulation to be cost effective requires consideration of alternatives. A minimum risk estimation provides no basis for assessing alternatives.

Second, a report by the IRLG demonstrates that, with respect to twenty or more substances, two or more of the regulatory agencies are considering or preparing regulatory action.(3) In some cases more than ten different statutes are involved. Encouragement to the agencies to coordinate their efforts is a good beginning, but provides no guidance on national priorities. Resources are limited and, absent some consideration of national priorities, coordination becomes a matter of exchange of information and timing. The Council should recommend that an effort be made to determine whether the benefits from the combined efforts of the agencies bear any reasonable relationship to the costs.

The Regulatory Council focuses mainly on health benefits from regulation. It is important to remember in making regulatory decisions that there are other benefits - social and economic benefits derived from the substance and, in appropriate cases, preserving the individual choices and preferences of the consumer.

Third, while one of the recommended Regulatory principles envisions coordinated development of multiple agency regulations controlling a specific substance or problem, the particular criteria espoused by the Regulatory Council on substitutes may be inconsistent with that principle. Unless a coordination mechanism is provided, the net effect of multiple agency reviews of substitutes within separate statutory authorizations could be a de facto ban of all functionally equivalent substances in a given industrial/ consumer area.

The Regulatory Council has recognized a division of each agency's interest derived from its statutory mission. Thus, a substance regulated for its risk to consumers -- on the basis of an available substitute -- may present little risk to workers, while the substitute itself may present a serious risk to workers. Two agencies, operating within their statutory scope and guided by the "substitution" test, may each take separate and inconsistent regulatory actions on the alternate substances without regard to a balancing of the relative consumer/worker risks or the quantification of such risks in the context of societal need for at least one of the substances.

Among the specific charges which the President gave the Regulatory Council was to improve regulatory management and make new rules more cost effective. It was also charged with analyzing the cumulative regulatory impact on economic sectors facing multiple regulatory action. The Council has not addressed in its statement what actions or procedures it plans to institute to ensure that the agencies will follow the principles and precepts the Council has endorsed. In reissuing its statement this matter should be specifically addressed. The Council should also explain how it will assess cumulative impact upon economic sectors facing multiple regulatory actions and how it will assure that those multiple regulations are cost effective and that the benefits will bear a reasonable relation to the cost.

IV. A Sound National Cancer Policy Should Address the Whole Problem Not Just a Segment

In the letter which this memorandum accompanies, AIHC has urged the Council to take two important actions in the progress to a sound national cancer policy.

1. The Council should reissue for public comment the statement on Regulation of Chemical Carcinogens after reissuance of the IRLG Report following evaluation of public comment. It is unfortunate that the Toxic Substance Strategy Committee draft Report and the Council's statement, which are interrelated and dependent on the IRLG Report in a significant way, were all issued prior to evaluation of public input on the underlying IRLG Report. We are confident these comments will not only lead to improvements in the various documents, but will also provide significant illumination of factors to be considered in a national cancer policy.

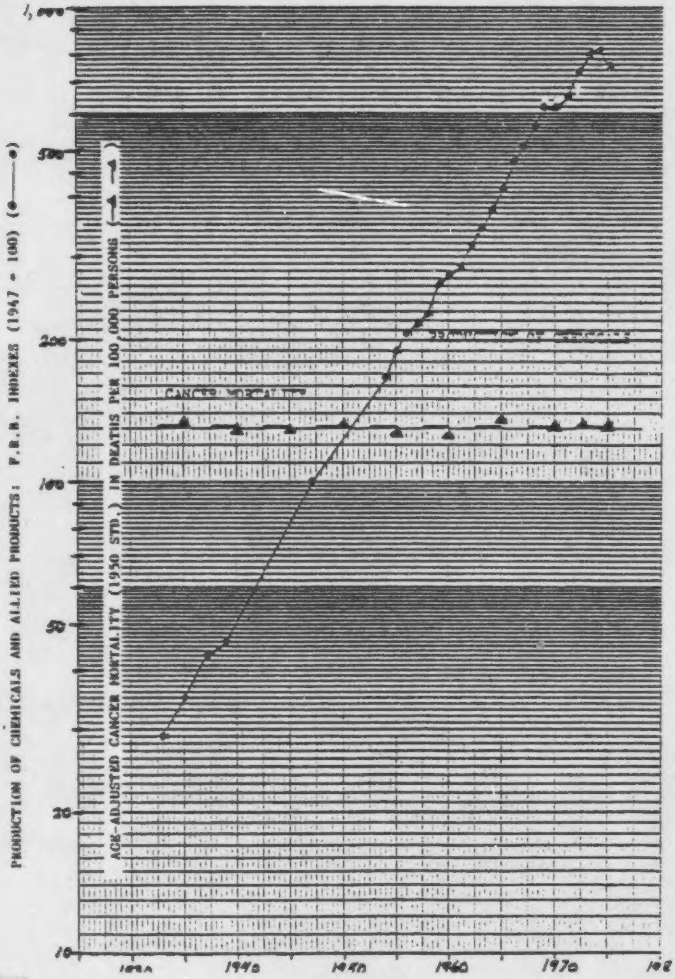
2. AIHC recommends that the Federal government provide a forum for launching of dialogue intended to provide a better and more sophisticated understanding of the relative contributors to cancer as a requisite to actions which government, industry, or individuals might take to reduce the incidence of cancer. The first essential step in the development of a sound national cancer policy is a dispassionate, objective and complete statement by the government of the scope of the national problem and the predominant causes of cancer. The national policy should be designed to address the whole problem, not just a small segment. (Eminent independent scientists in government, research and universities have identified lifestyle - smoking, diet and alcohol - as the predominant cause of cancer.)(4,5,6,7,8,9,10)

The Regulatory Council statement focuses on regulation of manufactured chemicals. This narrow focus and the failure to address lifestyle as the predominant cause of cancer results in a distorted perspective. Recitation of the national figures as to the medical costs of caring for cancer victims and the losses of earnings of those who died of cancer give the misleading perspective that the Regulatory Council is addressing the whole problem in its statement when in fact only a small segment is addressed. A policy based on that distorted perspective will achieve little reduction in the incidence of cancer and provides no basis for assessing the priorities for research and other policy objectives to achieve that reduction.

The narrow perspective of the Regulatory Council statement also leaves the erroneous impression that the predominant cause of cancer is industrial pollution from chemicals added to food, water and air or in the workplace. The table on the following page demonstrates that there is no correlation between the growth in production of industrial chemicals and mortality from cancer. The mortality rate has remained essentially flat when measured as the age adjusted number of deaths per 100,000 while industrial chemical production has increased by many orders of magnitude. Use of incidence figures leads to the same conclusion. The American Cancer Society reports that "[t]he overall incidence of cancer has decreased slightly in the past 25 years."(11) Dr. Phillip Handler, President of the National Academy of Sciences, referred also to the fact that the incidence of cancer has remained "approximately constant for a half century."(10)

TABLE I
ANNUAL PRODUCTION OF CHEMICALS (1933-1975) VS.
ANNUAL CANCER MORTALITY (1935-1975)

Direct testimony of James H. Jandl, In Re: Proposed Regulation for Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk (OSHA Docket No. H-090).



The cancer burden is world-wide, impacting both industrial and non-industrial nations. There is no discernible trend linking national cancer burdens to industrialization. The World Health Statistics Annual (1972-1973) identified Scotland as the country with the highest rate for males (on the basis of age adjusted cancer deaths per 100,000). The Netherlands had the highest rate for females. The United States is ranked 22nd for men and 21st for women behind non-industrial nations such as Switzerland, Northern Ireland and New Zealand.(11)

Dr. Phillip Handler, President of the National Academy of Sciences, stated recently that:

> "The possible effects of all known man-made chemicals, when totalled, would contribute only a miniscule fraction of all carcinogenesis in our population."(10)

Dr. John Higginson, Director of the International Agency for Research on Cancer said recently that those who seek to place the "blame" on industrial pollution are "confounded" by the fact that the cancer rate in Geneva, Switzerland, which has no industry, is higher than the rate in Birmingham, in the center of England's great concentration of industry.(4) Similarly, in the United States the Third National Cancer Survey (1969-71) found higher rates of cancer in "clean" cities - Minneapolis, Atlanta, San Francisco, and Dallas - than in "dirty" cities - Detroit, Pittsburgh and Birmingham.

The state-of-the-art of scientific risk identification and estimation is developing with almost explosive speed. The national cancer policy, therefore, should have built into it the flexibility to take account of new developments. The Regulatory Council appears to encourage generic regulations. If that is the intended meaning of the Council's statement, it should be re-evaluated. A generic policy can substitute administrative determinations for scientific evaluation. The inflexibility of generic administrative determinations can stand as a bar to new developments. The convenience and speed which are said to be the benefits of generic regulations are not a reasonable trade-off for administrative determinations which freeze science. The Regulatory Council should discourage any such generic regulations.

The speed with which new developments occur means also that any policy put forward today should be reconsidered periodically. Otherwise, programs which have lost their purpose will be continued and new programs which are needed will not come into existence. AIHC stands ready to assist the Regulatory Council in the important task of developing a sound national cancer policy.

V. Conclusion

We hope that no statement in this memorandum will be construed as in any way downgrading or minimizing the importance of controlling exposure to manufactured chemicals which may cause cancer. Cancer and its causes are a matter of great concern regardless of its source. AIHC and responsible leaders of industry are committed to its control. Our purpose is to urge perspective on the federal regulatory activities which the Council addressed in its statement "Regulation of Chemical

Carcinogens" and to suggest the next steps to move from the narrow focus of the Council's statement to a national cancer policy.

AIHC strongly recommends that the Regulatory Council:

1. Strengthen its generally laudable overall objectives, but clarify that the scope of the statement, relating principally to manufactured chemicals, addresses only a relatively small portion of the total cause and potential control of cancer.

2. Strengthen its guidance in matters of science by encouraging greater development and use of scientific risk assessment, emerging scientific data, and balancing of benefits or proposed regulations against costs of compliance.

3. Exert leadership and support or sponsorship for the IRLG to comprehensively review public comments on its "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" (44 Fed. Reg. 39858), and encourage issuance of an updated document by IRLG. Subsequently, the Regulatory Council should reissue its "Regulation of Chemical Carcinogens" statement to reflect the revised IRLG document.

4. Support and encourage a federal program that will provide a proper categorization and setting of priorities with reference to causes of cancer, inform the public objectively as to the predominant cause of cancer and initiate changes in policies to develop a national policy directed toward the total cancer burden.

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APPENDIX A

MEMBER COMPANIES
AMERICAN INDUSTRIAL HEALTH COUNCIL

Abbott Laboratories
Air Products & Chemicals, Inc.
Aluminum Company of America
Allied Chemical Corp.
American Bakeries
American Cyanamid Co.
American Hoechst Corp.
AMOCO Chemical Corp.
Apollo Colors, Inc.
ARCO Chemical Co.
Asarco, Inc.
Ashland Chemical Co., Div. of
  Ashland Oil, Inc.
Badische Corp.
BASF Wyandotte Corp.
Borden, Inc.
Borg-Warner Chemicals, Div. of
  Borg-Warner Corp.
Bristol-Myers
Buffalo Color Corp.
Burlington Industries, Inc.
Carus Corp.
Celanese Corp.
Certainteed Corp.
Chemplex Co.
Chesebrough-Ponds, Inc.
Chevron Chemical Co.
Church & Dwight Co.
Ciba-Geigy Corp.
Cities Service Co.
Clorox Company, The
Columbia Nitrogen Corp.
Cosden Oil & Chemical Co.
Dart Industries Inc.
Diamond Shamrock Corp.
Dow Chemical, U.S.A.
Dow Corning Corp.
Eastman Kodak Co.
Eaton Corp.
E. I. du Pont de Nemours & Co.
Eli Lilly and Co.
Essex Chemical Corp.
Ethyl Corp.
Evans Chemetics, Inc.
Exxon Chemical Co., U.S.A.
Fairmont Chemical Co., Inc.
Ferro Corp.
Firestone Tire & Rubber Co.
First Chemical Corp.
FMC Corp.
GAF Corp.
General Electric Co.
General Mills, Inc.
General Mills Chemicals, Inc.
Georgia Pacific Corp.
Goodrich Chemical Co., B.F.
Goodyear Tire & Rubber Co.
W.R. Grace & Co.
Great American Chemical Corp.
Guardian Chemical Corp.
Gulf Oil Chemicals Co., Div. of
  Gulf Oil Corp.
Halcon Research & Development Corp.
Hercules, Inc.
Hoffmann-La Roche, Inc.
Hooker Chemicals & Plastics Corp.
Hughson Chemicals, Lord Corp.
ICI Americas, Inc.
International Minerals & Chemical Corp.
Kay-Fries Chemicals, Inc.
Koppers Company, Inc.
Linden Chlorine Products, Inc.
Loctite Corp.
Mallinckrodt, Inc.
Merck & Co., Inc.
Merichem Co.
Milliken Chemicals, Div. of
  Milliken & Co.
Mobay Chemical Corp.
Mobil Chemical Co.
Monsanto Co.
Mooney Chemicals, Inc.
NALCO Chemical Co.
National Distillers & Chemical Corp.
National Steel Corp.
Neville Chemical Co.
NL Industries, Inc.
Northern Petrochemical Co.
Olin Corp.
Owens-Corning Fiberglass Corp.
Owens-Illinois, Inc.
Oxirane International
Pennwalt Corp.
Pfister Chemical Corp.
Pfizer, Inc., Chemicals Div.
Phillips Chemical Co., Div. of
  Phillips Petroleum Co.
Pope Chemical Corp.
PPG Industries, Inc.
Procter & Gamble Co.
Quaker Oats Co.
Reilly Tar & Chemical Corp.
Republic Steel Corp.
Revlon Foundation
Reynolds Metal Co.
Rhodia Inc.

Shell Chemical Co., Div. of
  Shell Oil Co.
Stauffer Chemical Company
Sun Chemical Corp.
Synalloy Corp.
Tenneco Chemicals, Inc.
3M Co., Commercial Chemicals Div.
Union Carbide Corp.
Uniroyal Chemical, Div. of Uniroyal, Inc.
United States Steel Corp.
UOP, Inc.
Upjohn Co., The
Velsicol Chemical Corp.
Virginia Chemicals, Inc.
Vulcan Materials Co., Chemicals Div.
Witco Chemical Corp.

APPENDIX B

AIHC Comments on the IRLG Report

SUMMARY

I. The IRLG Report Should Affirmatively Encourage Good Science by Clearly Distinguishing Between the Scientific and Regulatory Functions

1. The scientific function and regulatory function should be clearly distinguished. The scientific function of risk identification and risk estimation should not be mixed with the regulatory function of deciding what reasonable steps are required for risk avoidance. The objective of the scientific risk estimate should be to identify the most probable human risk based on evaluation of all the data, with an indication of the precision of the estimate. The function of the regulator is to assess benefits, safety factors, costs and other factors relevant to the societal/regulatory decision. Interjection of "conservative" models or assumptions in the scientific evaluation mixes the scientific function and the regulatory function. AIHC agrees with the Office of Science and Technology Policy that safety factors or conservatism should be addressed explicitly by the regulator and not concealed in some undisclosed way by adoption of conservative factors or models as part of the scientific evaluation.

2. The Report should encourage good science. Extrapolatioh models should be selected on the basis of scientific validity. The Report should reject "conservative" assumptions such as a direction to use the most sensitive model for extrapolation. The Report recognizes inter-species differences and the objective should be to find the animal model which is the best surrogate for man. If the Report makes clear that the most valid scientific extrapola-

tion models will be used and comparative metabolism will be used to select the most valid animal model, it will encourage the development of the data and encourage good science.

3. The IRLG should examine the Food and Drug risk analysis of aflatoxin in peanut products. FDA used human epidemiology to select the best animal model and attempted to make the most probable risk estimation without conservative assumptions. The regulatory options were realistically analyzed based on the scientific risk estimation.

4. To assure the highest quality and impartiality of the scientific risk estimations AIHC has proposed the creation of a science panel selected from nominees named by the national scientific academies and associations. The Office of Science and Technology Policy has also proposed a science panel as part of the National Toxicology Program under a committee from the regulatory agencies. AIHC believes that there is greater assurance of separation of the scientific and regulatory functions and of impartiality if a panel independent of the regulatory agencies is created as proposed by AIHC.

II. There Should Be Significant Modifications in How the IRLG Would Qualitatively Identify Carcinogenic Hazard

1. The Report biases the qualitative identification of carcinogenic risks by conservative assumptions. The result is a drive toward zero. All test results should be evaluated for quality and relevance. There should not be a bias in favor of positive results. All should be evaluated to determine whether they are valid evidence of carcinogenicity.

2. The Report recognizes inter-species metabolic differences, but in its bias in favor of positive results, fails to give appropriate scientific weight to the metabolic differences between man and the test animal. We urge the IRLG to encourage development of comparative metabolic data by assuring that the data when available will be used to improve the validity of extrapolation from animal data to man.

3. The Report places undue weight on short-term tests. Until the tests have been validated, they should, as the Office of Science and Technology Policy and the International Agency for Research on Cancer propose, be used only as screening devices for further testing.

4. The IRLG has adopted the hypothesis that all exposures to carcinogens are additive. Although there is evidence of additive or synergistic effects from exposures to some carcinogens, the Report itself recognizes that many substances act as inhibitors. The Report should identify the assertion of additivity of exposure as a hypothesis to be examined in each case. Where the data support a conclusion of additive, multiplicative or inhibitive effect, these data should be used in the risk estimation.

5. The IRLG fails to give due weight to negative human epidemiological studies. We urge the IRLG to adopt the more balanced view of the National Academy of Sciences and the EPA. Negative epidemiology can serve to mark the upper limit on human risk and to assess the extrapolation of animal data to man.

6. The IRLG report, by a determination that induction of benign tumors is the equivalent of induction of malignant tumors,

disregards the scientific reasons for making distinctions. AIHC agrees with the International Agency for Research on Cancer (IARC) that, if a substance is shown to induce only benign tumors, further investigation is required. AIHC also urges the IRLG to consider, as proposed by the IARC, the limited weight to be given to certain mouse neoplasms in evaluation of carcinogenicity.

IRLG recognizes that potency of carcinogens varies by several orders of magnitude. A substance which induces only benign tumors is of a completely different order of activity than one that produces highly malignant tumors.

To lump all substances that may be carcinogenic is scientifically unsound and confounds the IRLG's own comments on potency.

7. Historic experience in strains of test animals to assess test results must be used with caution. The incidence of spontaneous tumors may change in a colony over a period of time.

III. The IRLG Report Should Support Scientific Risk Estimation Methodology Selected on the Basis of Scientific Validity

1. Risk quantification methodology including selection of mathematical models should be made on the basis of scientific validity, not conservatism.

2. It may be reasonable to use a single mathematical model to make preliminary risk evaluations in setting priorities. Risk estimation, however, should not be made using conservative models or assumptions which improperly inject societal/regulatory values into the scientific process. The objective of the scientific function is to estimate the most probable human risk. Use of

"conservative" models presents a worst-case estimate biased in some undisclosed way. The FDA risk analysis of aflatoxin used human data to select the test species most like man and to evaluate extrapolation models. We urge IRLG to use a similar approach.

3. Mathematical models should be selected for scientific merit. IRLG was correct in not selecting any model as a generically valid model. AIHC urges the IRLG to express an open-mindedness in selection of a model or models on the basis of statistical evaluation of goodness-of-fit. We also urge the IRLG to encourage and support the improvement of models. The model selected should also reflect the biological data. The linear-through-zero and one-hit models which the Report emphasizes are inappropriate in those cases where the mechanism is epigenetic.

AIHC urges the IRLG to establish guidelines for evaluation and selection of models:

- Because no model can at present be selected generically on the basis of scientific merit, several models should be evaluated in each case and those with the highest relative validity used to generate a bracket of human risk.
- By evaluation of all data and exercise of scientific judgment the most probable risk can be estimated.

4. IRLG recognizes the importance of pharmacokinetic data in qualitative risk identification but does not underline the

importance of using these data in assessing the appropriateness of a model.

5. Risk estimation procedures should use human epidemiological data. The IRLG should recognize the use of negative human data in indicating the upper bound of human risk.

IV. Procedural Safeguards to Assure Due Process in the Identification, Estimation and Evaluation of Human Risk

Preliminary risk assessments made for purposes of priority setting should not be used to "blacklist" a substance. The commercial consequences of such a "blacklisting" cannot be erased by a final risk estimation; hence serious due process issues could arise. Moreover, the IRLG should focus on the method for suitable public input in the process of scientific evaluation.

FOOD SAFETY POLICY[*]

In dealing with food safety policy, there are three major ideas which may help lead to clear thinking. First, food safety policy is not the same as food safety science. Second, the ability of food safety science to resolve food safety policy problems is severely limited. Third, the food safety problems faced by this society are an integral part of the web of environmental health difficulties that this Nation is just beginning to grapple with. This set of realities makes the food safety debate one of the most searing and potentially most significant current debates about the kind of future that this society will have. Taking the points in inverse order:

Food safety problems are an important part of the environmental health situation. Currently, most cancers are of unknown origin, virtually all mental retardations and other birth defects are of unknown origin, and a relatively high incidence of spontaneous abortions and genetic damage to newborns in the society are of unknown origin. In the face of these facts, national researchers estimate that in excess of 60 percent of the cancer in this country has its origin at least in part in environmental causes. Similar conclusions about birth defects and genetic damage have been reached by researchers in their respective fields.

At the same time chemicals added to and occurring naturally in food have induced cancer, birth defects, and genetic damage in animals and/or bacteria and cells mediation systems.

It is no longer possible for any knowledgeable person to argue that the American food supply is without potential hazard. Since it has not been able to eliminate serious potential health hazards from the food supply this society now faces the problem of how to manage the food supply to minimize the health damage to which it contributes.

In this situation simple sounding ideas have appeal for policymakers. Currently, idea systems based on the assumption that we have sound complete scientific knowledge, supported by scientific demonstrable facts about the nature and extent of risks in the food supply are competing for the attention of decision and policymakers. One set of ideas argues that it is possible to rank various risks by kind or degree of risk and regulate more rigorously one set of risks—the big ones—other sets of risks the lesser ones.

Another set of ideas suggests that we can measure the risks currently accepted by the society (cigarette smoking and skindiving are two kinds of examples often cited) and allow the risks in the food supply to exist to a degree comparable to these already accepted risks. A third set of risk-based ideas asserts that specific food safety issues

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[*] James S. Turner, Swankin and Turner, Washington, D.C.

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should be measured by a risk benefit measure and those substances or policies which pose less risk than they supply benefits should be allowed or adopted.

Each of these proposals has its own set of limiting weaknesses. However, they all share the major disability that they do not address the problem of how to keep the food supply safe enough to eat. Specifically, each of them deals only with known risks which have been measured. Any risk-based food safety system ranking risks, comparing risks, or weighing risks against benefits excludes from policy consideration and management that overwhelmingly large set of safety problems that result from what is currently unknown, currently unmeasurable, or currently undetected. It does not focus on improving the health of or insuring safety for individual people.

Focusing on known and measurable risks to the exclusion of possible, potential, or even imaginable—but as yet undetected risks—is the most serious policy error currently clouding the food safety debate. A sounder policy approach would be to accept the fact that the food supply contains risks of all magnitude and all states of detectability from obvious to not even imagined. Then the policy should focus on those aspects of the food component problem which are manageable no matter the degree of risk. In this situation materials added to food, additives, pesticides, animal drugs, et cetera, become more appropriate for control by exclusioner limitation than naturally occurring toxicants. On the other hand, methods to diminish the amount present of naturally occurring toxicants became an appropriate focus for policy activity.

Already many food companies have begun policies of review on food safety matters beginning with the question "What can we remove from our food—in the way of chemicals, additives, residues, et cetera—because they are not necessary regardless of the kind or degree or absence of risk presented." Such a policy shifts the focus from controlling known and measurable risks to elimination of as many potential sources of risk as can be eliminated whether the potential risk is actually discovered and/or measured or not.

Step 1 of a sound policy is to remove all sources of potential risk that can be removed. Unless a strong case can be made for the use of an additive, the need for a pesticide residue, or the need for an animal drug, they should not be used. For those which have a strong need, then risk information must be vigorously ferreted out and organized. But organization should follow, not precede, a determination of the need for any nonnaturally occurring addition to the food supply.

Only when it is recognized that the potential lack of safety in materials added to the food supply is the starting point of a food safety policy can inroads be made into the actual damage being done by aspects of the food supply. Cancer, birth defects, and genetic damage are long-term problems of great seriousness with profound implications for the well-being of the future of this society. It is increasingly clear that some unknown portion of these problems are related to the consumption of food. Food safety policy must begin with this recognition.

Identify those added substances which cannot be dispensed with. Develop methods for the elimination of those naturally occurring substances which must be dispensed with. Then figure out which risks cannot be taken no matter how important the added or naturally occurring substances. This is the beginning of a policy approach to food safety.

The next step could be to expend meaningful resources on the continuous scientific monitoring of substances which find their way into the food supply under this kind of a policy. Sophisticated epidemiological techniques should be used to monitor, on a long-term basis, any substance so important it must be added to the food supply and not so unsafe it must be excluded, or any naturally occurring substance which cannot be eliminated and which is safe enough to live with. Such an epidemiological program could provide a growing data base on food safety matters related to substances thought to be safe enough to allow in the food supply. The four step policy suggested here is:

1. Identify essential additive materials;
2. Identify naturally occurring potential dangers which cannot yet be eliminated;
3. Exclude, limit, or otherwise control materials that pose some risk but not so much that they should be excluded;
4. Systematically monitor those substances allowed to be added to food and those naturally occurring which potentially pose a hazard.

This four step policy is a rough outline of a policy that begins from a point of view that does not initially assume that all existing risks are known, measurable and detectable. Any program that assumes the ability to identify, quantify, and evaluate risks present in food will lead to serious damage to individual members of the population.

Resting food safety policy on the assumption that all existing risks are known, measurable and easy to evaluate is the primary mistake made by many individuals who propose food safety policies. The hazards of concern in the food safety debate are too integrally related to the general environmental hazard problems of the society for it to be assumed that we have found the risks and they are ours to be eradicated. The biggest food safety problem is that most of what is harmful, more likely than not, is still unknown. This is the only sound starting point for a food safety policy. Misunderstanding the nature of the risk is the first mistake that policymakers must guard against.

The second mistake that policymakers must avoid is the assumption that food safety science can solve food safety problems. Policymakers must learn that science is limited in its ability to determine food safety policy. In addition to the fact that the suggested potential problems of safety contained in the food supply are unknown, it is also a fact that the ability of science to be conclusive even in areas where it is highly developed is severely limited.

When a scientist argues that saccharin should be phased out of the food supply because it is a cancer-causing substance he is not giving a science answer. Only the part of his recommendation concerning the cancer-causing nature of the chemical is scientific. Whether the substance should be immediately banned, phased out, or allowed in the food supply is a policy recommendation on which a scientific researcher is not particularly qualified to comment. Discussions of the Delaney anticancer clause are included (attachment A) in an effort to present the policy arguments about how to respond to limited scientific material.

The serious limitations of science as a substitute for sound food safety policy are set out in attachments B and C. The fact that the food safety issue is a policy and not a science issue is nicely set out in attachment D by a food company executive who has thought extensively about these problems. In addition to recognizing the fact that ordering or measuring risks cannot be the starting point of an effective food safety problem, policymakers must also recognize that science, even where it is measuring and evaluating risks, is a severely limited tool.

Ordering and/or weighing food safety risk is not a sound way to begin a food safety problem because the biggest risks are the unknown risks which by their very nature cannot be ordered, measured, or weighed. Even where risks are known or at least highly probable science is severely limited in describing, measuring, or otherwise characterizing them. This leaves policymakers with relatively small help from science and a not very clear idea of what task they are undertaking.

In this situation it is tempting for policymakers, whether regulatory or legislative, to direct "prestigious" academic bodies to mull the questions over more in order to buy political time rather than to produce a policy answer. The problem with this maneuver is that time always runs out and the policy issues are not being addressed because the policymakers have ducked the issue. What is important to recognize, however, is the fact that policymakers have a distinct skill which has as much expertise to its use as the skills of the academic/scientific world.

Serious attention must be paid by the policymakers to their own unique expertise in policy developments. Policymakers have a legitimate role to play in shaping and resolving national health and safety issues such as the safety of the food supply. Continued deferring of hard food safety questions to scientific bodies will lead eventually to Congress having delegated away its health and safety authority. The attached paper "How Safe Is Safe" (attachment B): attempts to set out the distinction between science and policy in a way useful to the consumers' point of view to the food safety debate.

Managing known, measurable, or suspected risks, as difficult as that task is, makes up only the smallest part of the food safety policy problem. Dealing with unknown, unmeasured, or unsuspected risks is where the heart of the policy problem lies. Because dealing with known measurable or suspected risks seems more immediate and easier to manage, it continuously becomes the focus of the food safety debate. In fact, it is possible if not probable that the unknown, unmeasurable, or unsuspected risks pose the greater threats to the future well-being of this society. To the extent that this is true, certain policy approaches make more sense than others.

To the extent that managing unknown, unmeasured, or unsuspected risk is the focus of food safety problems, the following policy approaches make sense. These are examples; others need to be developed.

1. Control what can be controlled. To the extent that natural dangers exist, substances which might increase these natural dangers should be curtailed.

2. To the extent that possible dangers are allowed or discovered in the food supply, continuous epidemical monitoring of these possible dangers should be undertaken.

3. Scientific examination of food safety problems should be organized to increase and upgrade the available scientific data. A proposed testing system to achieve this goal is attached.

Proposed testing system

Currently a substance designed for use in food is tested at the proposer's expense and the results are given to the FDA for evaluation. It could be possible for the FDA to certify a set of laboratories for testing; receive a proposal for testing of a substance from a proponent and then refer the substance for testing on a randomized basis to a certified laboratory. The testing would be paid for by the proposer as is now the case, but the results would be relied on for prima facie disposition of the risk question.

Such a system has already been introduced in legislation in the U.S. Senate.

[ATTACHMENT A]

THE DELANEY ANTICANCER CLAUSE: A MODEL ENVIRONMENTAL PROTECTION LAW

(By James E. Turner*)

I. INTRODUCTION

In October 1969, the artificial sweetener cyclamate was banned from sale in the United States by Secretary of Health, Education, and Welfare Robert Finch. To justify his action legally Finch chose to rely[1] on the so-called Delany anticancer clause of the Food, Drug, and Cosmetic Act of 1938. Consequently, the Delaney clause, with its requirement that any substance producing cancer in animals be removed from the American food supply,[2] became an immediate center of controversy. The Secretary himself criticized the clause as an undue restriction on administrative decisionmaking and as an unscientific limitation on scientific discretion.[3] When asked if the Delaney clause should be modified, Food and Drug Administration Commissioner Charles C. Edwards reflected Secretary Finch's view in replying:

> I think the scientific community is rather well split on this issue. There are those who feel that it is just what it ought to be right now. My personal view and

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[1] "I have acted under the provisions of * * * the so-called Delaney amendment, enacted eleven years ago, which states that any food additive must be removed from the market if it has been shown to cause cancer when fed to humans or animals * * * because I am required to do so." Announcement of cyclamate ban, press release of Secretary Finch, Oct. 18, 1969, at 3.

[2] "[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." Food additives Amendment of 1958, sec. 409(c)(3)(A), 21 U.S.C. sec. 348(c)(3)(A) (1964).

[3] "But who is to say that using Fresca or some other diet drink * * * isn't better for you than the problems of overweight or diabetes." Finch Takes Position Against Delaney Clause, Food Chemical News, Nov. 10, 1969, at 3.

> that of the FDA is that we have to have more flexibility of interpretation or we are put into a position we were with cyclamates—all or nothing.[4]

The contrary point of view was reported to the Surgeon General in 1970 by an eight-member committee of scientists with a staff of six senior scientists from the National Cancer Institute. After reviewing the state of cancer research and its relation to the Delaney clause, the committee stated:

> It is essential to recognize that no level of exposure to a carcinogenic substance, however low it might be, can be established to be a "safe level" for man * * *. The current legislation in the field of food additives, with its "anti-cancer clause," is based on this principle.[5]

Although the Delaney clause has faced criticism from some quarters, careful analysis of the clause reveals that it seems to serve well as a vehicle for the proper balancing of administrative discretion and scientific independence on one hand with public protection on the other; because of the analogous policy conflicts that arise in many areas of consumer concern, the clause represents a valuable model for all environmental protection legislation.

II. THE STRUCTURE OF PROTECTION UNDER THE FOOD, DRUG, AND COSMETIC ACT OF 1938

Prior to the enactment of the Food, Drug, and Cosmetic Act of 1938, a food was considered adulterated, and therefore excluded from interstate commerce, if it contained any added poisonous or deleterious ingredient that might render it injurious to health.[6] This state of the law proved to be unacceptable because, before a food could be barred from the national market, the Government had the obligation of showing affirmatively that it contained an added poisonous or deleterious substance which might be harmful under normal conditions of use.[7] In passing the 1938 act to alleviate this problem of proof, Congress altered food protection law in two ways changing both essential definitions and basic operating procedures. First, section 402(a) redefined adulteration:

> A food shall be deemed to be adulterated. * * * (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406. * * *[8]

An unsafe substance was defined in section 406(a):

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). * * *[9]

Second, procedures were prescribed that for the first time allowed poisonous or deleterious substances to be added to the food supply if the amount was within tolerances promulgated as safe by the Secretary.[10] The new definition of adulteration, however, did not resolve the chronic burden-of-proof problem. Under the 1938 act the evidentiary issue was simply moved back one step, and the Food and Drug Administration (FDA) found itself compelled to show affirmatively in the first instance that a particular chemical was poisonous or deleterious.[11]

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[4] Interview with Charles C. Edwards, Commissioner, Food and Drug Administration, in U.S. News & World Report, Apr. 19, 1971, at 52.

[5] National Institutes of Health and National Cancer Institute, Evaluation of Environmental Carcinogens, Apr. 22, 1970 (Report to the Surgeon General, USPHS, by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens).

[6] Food and Drug Act of 1906, ch. 3915, secs. 2, 7, 34 Stat. 768.

[7] 1933 FDA Annual Report 14.

[8] Food, Drug, and Cosmetic Act of 1938, ch. 675, sec. 402(a), 52 Stat. 1040.

[9] Id. § 406(a).

The difficulty in the application of section 406's test to various chemical substances arose because the drafters of the section attempted to define an acceptable level of human risk by utilizing the constructs "safe" and "unsafe." From the legislative history of the act it clearly is demonstrable that by using the words "poisonous" and "deleterious" [12] Congress sought to designate all unsafe substances. Understood in this way, sections 402 and 406 form a legal non sequitur.

The circular nature of the food protection device becomes evident when the word "unsafe" is substituted for the terms "poisonous" or "deleterious" as they occur in the act. Section 402(a)(2) would read: "A food shall be deemed to be adulterated * * * if it bears or contains any added unsafe substance which is unsafe within the meaning of section 406." Section 406 would read: "Any unsafe substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for the purposes of the application of clause (2) of section 402(a)." Manifestly, Congress attempted to devise a formula for establishing tolerances for poisonous—unsafe—ingredients in food. Just as clearly, however, by defining circularly the term "unsafe," Congress forced the FDA to prove in each instance the poisonous or deleterious nature of the chemicals. Often this placed the FDA in the position of attempting to answer legally, scientific questions unanswerable in the laboratory. The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health underscored the problem, stating: "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods." [13] Because of its definitional difficulties, the

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[10] Food, Drug, and Cosmetic Act of 1938, sec. 409, 21 U.S.C. sec. 348 (1964). In approaching the problem of control from this angle, one Senate committee report stated: "[T]he amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quality of poisons sufficient to jeopardize health." S. Rep. No. 493, 73d Congress, 2d session 4 (1934); see C. Dunn, Federal Food, Drug, and Cosmetic Act 113 (1938). In addition, the Senate committee report commented on the tolerance provisions as follows: "In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to [very] small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, and dangerously toxic substances to foods, as for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture packaging and by use of refrigeration for the finished product." S. Rept. No. 493, 73d Congress 2d session 4 (1934).

[11] "Under the law as it was * * * [after 1938] the FDA could not stop the use of a chemical simply because it was questionable, or had not been adequately tested. It was necessary to be able to prove in court that the chemical was poisonous or deleterious." T. Christopher, "Cases and Materials on Food and Drug Law 468" (1966).

[12] Webster's New International Dictionary (2d ed. 1957) defines "poisonous" as "[h]aving the properties or effects of poison;" i.e., "[a]ny agent which, introduced * * * into an organism, may chemically produce an injurious or delay effect." It defines "deleterious" as "hurtful," "noxious;" i.e., "unwholesome."

[13] "White House Conference on Food, Nutrition and Health, Final Report 130" (1969).

1938 act, like its predecessor, proved to be ineffective and food protection problems increased.[14]

Faced with the nearly impossible task of establishing safety for every controversial chemical, the FDA once again sought changes in the law. Between 1950 and 1953 New York Congressman James J. Delaney conducted a series of hearings into the nature and use of chemicals added to the food supply.[15] From these hearings three major pieces of legislation resulted: the Pesticide Amendments of 1954,[16] the Food Additives Amendment of 1958,[17] of which the Delaney clause is a part; and the Color Additive Amendments of 1960.[18] The originally straightforward prohibition of unnecessary or avoidable poisonous or deleterious substances from food became the complicated prohibition of:

> (A) * * * any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agriculture commodity; (ii) a food additive; or (iii) a color additive) which is unsafe within the meaning of secton 346 * * * or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of 346a(a) * * * or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 * * *.[19]

Each piece of inserted language, covering pesticides, food additives, and color additives, represents an involved regulatory system spelled out in detail within the act. The administrative discretion granted by this machinery requires the FDA to weigh the value of each proposed chemical use on a scale that balances the rights of the chemical producer against those of the general public; however, proof of safety remains the objective of each part of the act.

The pesticide, food additive, and color laws all contain essentially the same regulatory structure, consisting of a chemical-by-chemical analysis by "the Secretary." This authority has been delegated to the Commissioner of Food and Drugs for food and color additives and to the Administrator of the Environmental Protection Agency for pesticide chemicals. In each case the process begins by the filing of a petition seeking a ruling by the Secretary that either allows the chemical to be used, or bars its use, in the ways sought by the petitioner. The decision of the Secretary comes in the form of an order that specifies the ways in which the chemical may be properly used. Detailed procedural rules govern the process that the Secretary and all interested parties must follow from the time the petition is filed until the time of a final order and dictate the way in which the appeals from the final order are to be brought to the attention of the courts.[20] It should be noted that the complex statutory apparatus leaves unsolved the definitional problems inherent in the use of the word "unsafe"—the same problem that caused the 1906 and 1938 food protection laws to founder.[21]

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[14] The definitional problems could have been obviated if the section had been drafted without reference to the notion of safety. For example, it could have read "no chemical substance shall be added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." The tolerance-setting procedure under this language would be used to determine whether a chemical was avoidable or was required in food production. This was apparently the very concept that Congress intended to introduce into the law. At this stage the FDA could defer to scientific judgments of safety when they existed.

[15] See Hearings on H.R. 74 Before the House Select Commission To Investigate the Use of Chemicals in Food Products, 81st Congress, 2d Session (1951).

[16] Act of July 22, 1954, ch. 559, 68 Stat. 511 (now 21 U.S.C. 346a (1964)).

[17] Act of Sept. 6, 1958, Public Law 85–929, 72 Stat. 1784 (codified in scattered sections of 21 U.S.C.).

[18] Act of July 12, 1960, Public Law No. 86-617, 74 Stat. 397 (codified in scattered sections of 21 U.S.C.).

[19] 21 U.S.C. 342(a)(2) (1964).

[20] 21 C.F.R. sec. 120 (1971) (pesticides); 21 C.F.R. sec. 121 (1971) (food additives); 21 C.F.R. sec. 8 (1971) (color additives).

III. THE PROOF-OF-SAFETY PROBLEM—UNSUCCESSFUL ATTEMPTS TO SOLVE IT

The Food Additives Amendment of 1958 contains three distinct attempts to alleviate the FDA's burden-of-proof problem: (1) the generally recognized as safe (GRAS) approach that resulted in the GRAS list of chemicals approved by the FDA for addition to foods;[22] (2) the Delaney anticancer clause that bans from food any substance which causes cancer when fed to animals,[23] and (3) the administrative structure that emanated from FDA regulations designed to evaluate item by item any chemicals which do not fall into either category one or two.[24] Each of these three legal stratagems endeavored to circumvent the problem of scientific uncertainty, but only the Delaney clause succeeded. Before detailing the accomplishments of the Delaney clause, the reasons for the failure of the other two mechanisms should be outlined for comparative purposes. Legislation that effectively controls chemical contamination of the environment must seek to block the use of substances that present undue risk without putting unreasonable restraints on chemicals that provide important benefits to the public. To initiate the GRAS procedure, the Food and Drug Administration asked 900 scientists to comment on the safety of the first substances proposed for the GRAS list. Rather than achieving the scientific consensus assumed possible by the GRAS theory, the FDA harvested a scattering of opinions. Of the 900 scientists questioned, 350 replied with only 194 or 21 percent of the total group ratifying the entire list. The performance of the FDA in accurately predicting the safety of specific chemicals, even after some doubt had been raised, was similarly imperfect. The FDA, for example, dismissed the complaints of a number of scientists against safrole,[25] vitamin D, and most notably cyclamate, only to find it necessary to act against the challenged chemicals in subsequent years. Thus the GRAS list mode of procedure proved to be ineffective in discriminating between safe and unsafe substances because the system presented the same problem of scientific choice that the earlier acts had been unable to deal with. Where the agency earlier had tried to choose which chemicals and which foods were safe, it now foundered trying to choose which scientists were the best judges of safety. An FDA memorandum spelled out the guiding principle of this choice.

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[21] One commentator described the food additives amendment—and would probably say the same about the other two amendments—as "an example of law seeking to meet the problems that arise as side effects of scientific, economic and technological progress." T. Christopher, supra note 11, at 130. Actually it might be more accurate to say that these three amendments are examples of legislation seeking desperately to deal with the problems created by poor legislative drafting.

[22] Section 201(s) of the 1958 act reads: "The term food additive means any substance * * * not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use * * *." A parenthetical insert into this section set up a different standard for substances used prior to Jan. 1, 1958, saying "or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food." 21 U.S.C. 321(s) (1964). Essentially the same provision exists in both the pesticide amendment and the color additive amendments. Section 408(a) of the 1954 act reads: "Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pestcide chemicals as safe for use * * * shall be deemed unsafe * * * unless * * *." 21 U.S.C. 346a(1) (1964). Sec. 606(b)(4) of the 1960 act reads: "[A] color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in Sec. [321(s)] * * *." 21 U.S.C. 376(b)(4) (1964).

[23] The Delaney clause for food additives is contained in sec. 409(c)(3(A) of the Food Additives Amendment of 1958, 21 U.S.C. 348(c)(3)(A) (1964). It is also repeated in the Color Additive Amendments of 1960, sec. 706(b)(5)(B), 21 U.S.C. 376(b)(5)(B) (1964) that reads: "a color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal * * *." Whether the Delaney clause applies to pesticide chemicals is a more difficult question about which there is considerable controversy. The Secretary's Commission on Pesticides wrote as if the clause could be interpreted to apply to pesticide chemicals; however, the definition of food additives expressly excludes "a pesticide chemical in or on a raw agricultural commodity * * *." Food Additives Amendment of 1958, sec. 201(s)(1), 21 U.S.C. 321(s)(1) (1964). Since there is no anticancer clause in the Pesticide amendment, it would appear that pesticides do not fall under the prohibition of the Delaney clause.

[24] This is the regulatory procedure outlined above and is essentially the same for pesticide chemicals, food additives, and color additives.

> In our final evaluation of the safety of a substance we have taken cognizance of the fact that all opinions are not of equal value and thus have weighed most heavily the opinions of scientifically recognized and often world-renowned experts.[26]

Under this pick and choose procedure the basic GRAS list grew to approximately 700 items with various loopholes and exceptions allowing as many as another 1,000 items to be treated as on the GRAS list by the FDA.[27] Food manufacturers, faced with a minimum of an estimated 2 years of study[28] before gaining permission to market a new additive, sought to achieve recognition of their chemicals through the loopholes in the GRAS list procedure. By the end of 1970 the situation had become so unwieldy that the agency moved to revise the entire GRAS procedure by attempting to reintroduce suspect chemicals currently on the GRAS list into the chemical-by-chemical investigation.[29]

As previously noted, the chemical-by-chemical procedure relies on the ability of scientists to distinguish safe from unsafe substances. That portion of the act authorizing this approach states: "No * * * regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. * * *"[30] All parties to the discussion of the 1958 Food Additives Amendment accepted the assumption that safety or the lack of it could be established in each case, and accordingly, the FDA issued a regulatory definition of safety that said, "'Safe' means that there *is convincing evidence* which establishes with reasonable certainty that no harm will result from the intended use of the food additive."[31] Faced with reviewing the GRAS list that contained many items for which scant, controversial, or no evidence existed, the FDA, interestingly enough, moved to redefine "safe." "'Safe' must be understood to connote that the Food and Drug Administration, after reviewing *all available evidence*, can conclude there is no significant risk of harm from using the substance as intended."[32] This second definition allows untested or only partially tested chemicals to be added to the food supply, while the former definition required the initial presentation of some convincing evidence of safety. The change in definition represents a significant erosion of the safety concept, one of the unfortunate side effects that results when a regulatory agency expected to enforce policy is required to resolve scientific conflicts. The Surgeon General's committee on low-level carcinogens demonstrated the folly of the FDA's new safety definition. It reported that bioassays are incapable of detecting carcinogenic effects below the 10-percent level, and therefore so-called negative data are grossly inadequate to give assurances of safety for man.[33] More importantly, leading scientists[34] are increasingly making this same argument about the chemicals related to genetic problems, birth defects, and mental retardation. The current FDA attempt to revise the GRAS list and its redefinition of safety concede the difficulty of giving empirical meaning to the term "unsafe" while the whole area is the subject of scientific controversy. This difficulty is further demonstrated by the FDA's new interim regulation policy.

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[25] "Safrole" is the ingredient used for flavoring in root beer.

[26] FDA Division of Pharmacology and Food memorandum, Sept. 2, 1959.

[27] The details of this situation are spelled out in J. Turner, "The Chemical Feast, the Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration," 153–59, 162–63 (1970).

[28] Hearings on H.R. 8112 before a subcommittee of the House Committee on Interstate and Foreign Commerce, 85th Congress, 1st and 2d sessions 60 (1957–58) (remarks of FDA Commissioner Larrick).

[29] Food Additives, 35 Federal Register 18,623 (1970).

[30] Food Additives Amendment of 1958, sec. 409(c)(3)(A), 21 U.S.C. 348(c)(3)(A) (1964).

> If after a responsible and substantial question of safety has been raised regarding a substance previously listed as GRAS the main weight of the scientific evidence still indicates safety (at least within certain limits), an interim food additive regulation will be proposed. This will permit further scientific investigations to define the conditions of safe use for a food additive regulation of indefinite duration.[35]

This statement seems to be at variance with the provision of the act that requires that "no such regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe * * *."[36] The FDA, however, argues that an interim time period serves merely as one more condition of use under the law, and this interpretation has been upheld in Federal district court.[37] The practice of issuing interim regulations further erodes the assumption that the food supply contains only safe chemicals.

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[31] 21 C.F.R. sec. 121.1(i) (1971) (emphasis added). Commenting on the safety provision, Charles Wesley Dunn, the general counsel for the Grocery Manufacturers of America stated: "Such [a] requirement is basically a pretesting one for new food additives. * * * Whereas the FDC Act now prohibits a food that is unsafe, this prohibition normally applies after the food is sold and consumed, and its enforcement may be long delayed for various reasons. * * * [m]oreover in such an enforcement proceeding the Government has the burden of proving that the food is unsafe, whereas this requirement would instead compel the manufacturer of a food to prove in advance that it is safe." Hearings on H.R. 8112 supra note 28.

[32] Food Additives, 35 Federal Register 18,623, 18,624 (1970) (emphasis added).

[33] National Institutes of Health and National Cancer Institute, supra note 5.

[34] Examples of scientists who are concerned with chemicals causing birth defects and genetic damage include Dr. Samuel Epstein of Case Western Reserve University, Dr. James Crow of the University of Wisconsin, Dr. John W. Olney of Washington University, and Dr. Marvin Legator of the FDA.

[35] Food Additives, 35 Federal Register 18,623, 18,624 (1970).

[36] Food Additives Amendment of 1958, sec. 409(c)(3), 21 U.S.C. 348(c)(3) (1964).

[37] The oral opinion of Judge Gerhard Gesell was reported in Food Chemical News, July 12, 1971, at 17.

The FDA, after 65 years of failure, still struggles to solve scientific controversies about safety with legal tools. One apparently overlooked fact underlies this struggle. When scientists agree that a chemical is either safe or unsafe, no controversy about its use erupts. Only when a scientist challenges the label of "safe" attached to a chemical or class of chemicals by other scientists does the FDA engage its balancing mechanism. Otherwise chemicals enter the food supply virtually unnoticed. As a result, whenever it enters a controversy the FDA overrules one set of scientifically supported arguments with a legal or regulatory judgment.

The twisting and turning of the food and drug laws since 1906 resulted from using the word "safety" to denote two distinct concepts. First, it includes the scientific observation that a chemical additive or food does not cause damage to humans. Second, it includes the policy judgment that even though a chemical might cause injury to a human, the damage it causes is outweighed by the benefits it imparts. Only the Delaney clause of the Food and Drug Act escapes this pitfall by avoiding any reference to either concept of safety. Instead, it allows scientists to ascertain the degree of risk presented by the use of a particular chemical and assigns policymakers the task of judging whether the scientifically defined risk is acceptable to society. For this reason it serves as a model for all other environmental protection legislation. Despite the simple logic underlying the clause, and despite its ready applicability to other regulatory fields, this clause has often been misunderstood by regulators and the public alike.

IV. THE DELANEY CLAUSE: A MODEL FOR ENVIRONMENTAL PROTECTION LEGISLATION

A. *Misunderstanding the Delaney clause*

Food and Drug Commissioner Charles C. Edwards restated accurately the misunderstanding of the Delaney clause when he said of it:

> My personal view and that of the FDA is that we have to have more flexibility of interpretation or we are put into the position that we were with cyclamates—all or nothing. And it becomes a highly emotional issue at that point, allowing no discretion on our part or anyone else's.[38]

This statement implies that but for the Delaney clause the FDA would have allowed cyclamates to remain in the food supply in some amount even though this chemical causes cancer in rats. The Commissioner's characterization of the Delaney amendment as a usurpation of administrative discretion is incongruous because other parts of this food protection law, although operating more slowly than the anticancer clause, also would have required cyclamates to be completely banned from the food supply. At the onset of the cyclamate controversy, the chemical was generally recognized as safe by the FDA. After a substantial safety question was raised, the Secretary officially removed cyclamates from the GRAS list. At this point the law, absent the Delaney clause, requires that the chemical be shown to be safe before a petition can be granted allowing its addition to food.[39] In view of the state of scientific knowledge about cancer-causing substances, it is unlikely that cyclamate could have met this burden of proof; therefore, the chemical could have been removed from the food supply without reference to the Delaney clause. In fact, some of the most vigorous critics of the Delaney clause call it an unnecessary duplication of already existing authority.

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[38] See Interview with Charles C. Edwards, supra note 4.

[39] Food Additives Amendment of 1958, sec. 409(c)(3), 21 U.S.C. 348(c)(3)(A) (1964).

When the Commissioner asks for "discretion" to decide when a chemical that causes cancer in animals can still be used in food for man, he is asking for the discretion to decide an issue that thousands of cancer researchers have been unable to resolve. The dangers of this position were put forth accurately by former Secretary of Health, Education, and Welfare, Arthur S. Flemming:

> The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent.
>
> * * * * * * *
>
> As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how the provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.[40]

The fact that the country's highest food and drug officials still believe that this kind of discretion should be granted demonstrates the need for more effective policy setting by Congress.

B. Expanding the Delaney Clause to Other Areas of Environmental Protection Legislation

From the FDA's experience in attempting to differentiate between safe and unsafe substances, it seems apparent that in order to shield the environment from further chemical contamination, the policy issues and the scientific issues, although interrelated, must be approached separately. The report to the Surgeon General on environmental carcinogens clearly defined the problem and divided the scientific and policy responsibility. "While science can provide quantitative information regarding maximum risk levels, the task of ultimately selecting scocially acceptable levels of human risk rests with society and its political leaders."[41] The role of the scientist is to describe physical phenomena—this chemical caused lesions in mouse brains under these conditions; that chemical caused cancer when fed to mice in certain quantities; those chemicals caused birth deformities when injected into chickens in designated amounts at certain ages. Scientists can offer less definite but still important scientific opinions on the degree to which damage to man can be predicted from damage to animals. Without knowing the levels of risk that society will tolerate, however, scientists cannot effectively differentiate between "safe" and "unsafe" substances.

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[40] Hearings on H.R. 7624 Before a Subcommittee of the House Committee on Interstate and Foreign Commerce, 86th Congress, 2d session 501 (1960). The members of the committee that reported to the Surgeon General on low levels of environmental carcinogens considered the arguments made by Secretary Flemming so important that they inserted the entire statement of the former Secretary in their report. Following the statement they added this note: "The scientific basis on which the Government's position was established in 1960 remains valid. The progress of knowledge in carcinogenesis in the last decade has only strengthened the points made in Secretary Flemming's testimony." National Institutes of Health and National Cancer Institute, supra note 5.

[41] National Institutes of Health and National Cancer Institute, supra note 5, at 14.

Congress, on the other hand, taking into consideration the certainty or relevancy of the scientific findings, must set broad policy guidelines. Several issues suggest themselves as important for the consideration of the Nation's policymakers. Which purposes served by chemicals are worth the apparently increasing risk of their use in foods? Resolving this issue involves a reassessment of the "required for" or "unavoidable in" food production concept of section 406. If additional uses of chemicals are found necessary to improve the food supply, these concepts could be expanded.[42] In addition, Congress must determine which extrapolations from animals can be made to man. In the cancer area it is policy that if a chemical affects animals it will not be given to humans.[43] This practice was adopted because under the present state of scientific knowledge a safe tolerance for man of a substance that produces cancer in animals cannot be established.[44] What chemicals should be added to the "zero tolerance" list now containing only carcinogens? Already chemicals causing birth defects and genetic damage in animals have been suggested for addition to the list. Congress must collect and review the evidence that other irreversible biological damage can be caused by chemicals and set a "zero tolerance" policy for these areas where necessary.

The Delaney clause can serve as a model for environmental protection legislation because it delegates to scientists the responsibility for making scientific judgments and to Congress the task of making policy decisions. The scientist, after an analysis of all technical data, specifies the degree of risk that would result if any amount of known carcinogens were allowed in the Nation's food supply; Congress, after considering all other relevant information, determines that the risk is unacceptable. The FDA is then charged with the responsibility of removing carcinogenic chemicals from the food supply. The procedure outlined for developing a new food protection or any other environmental protection law should not include any effort to define "safety." Rather, scientists should describe a degree of risk as accurately as science allows. Congress then should decide whether that risk is worth taking. To begin the development of a more effective food protection law, the report to the Surgeon General enunciated one additional fundamental point. "Chemicals should be subjected to scientific scrutiny rather than given individual 'rights': they must be considered potentially guilty unless and until proven innocent." [45] The authors of that report directed their comment at carcinogens, but the same observations may now be made for chemicals relating to genetic damage or birth defects.

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[42] The Food Safety Panel of the White House Conference suggested some additional criteria that Congress might consider: "[That] no additional chemicals should be permitted in or on foods unless: They have been shown with reasonable certainty to be safe on the basis of the best scientific procedures available for the evaluation of safety and meet one or more of the following criteria: 1. They have been shown by appropriate test to be significantly less toxic than food additives currently employed for the same purpose; 2. they significantly improve the quality or acceptability of the food; 3. their use results in a significant increase in the food supply; 4. they improve the nutritive value of the food; and 5. their use results in a decrease in the cost of food to the consumer." White House Conference on Food, Nutrition and Health, supra note 13.

[43] Food Additives Amendment of 1958, sec. 409(c)(3), 21 U.S.C. 348(c)(3)(A) (1964).

[44] National Institutes of Health and National Cancer Institute, supra note 5, at 15.

[45] Id. at 15.

V. CONCLUSION

The nearly uninhibited addition of chemicals to the environment for the last several decades lies at the heart of the so-called environmental crisis. To control this use of chemicals requires a new combination of scientific expertise and legal policy. The drafters of the Delaney clause of the current food protection law were successful in writing into the legislation a proper balancing of the policy function and the scientific function. Congress heard scientists describe the level of known and unknown risk associated with cancer-causing chemicals. It set the policy that no chemical known to cause cancer in animals would be allowed in the food supply. The regulatory agency was assigned the scientific task of distinguishing those chemicals that cause cancer in animals from those that do not. The Delaney clause sets clear public policy and allows complete scientific freedom.

Congress, by setting the public policy concerning cancer-causing chemicals itself and by assigning the scientific implementation of that policy to the agency that regulates food, established a procedure for effectively weighing environmental dangers and acting to prevent them. All chemicals—whether they be pesticides in or on foods, industrial chemicals that contaminate the water or air, hazardous substances that are used in the home, or any one of hundreds of other environmental pollutants used in this society—must be subjected to a rationalized policy. Congress, guided by the state of scientific knowledge, must place limits on the risks to be assumed by society; the appropriate regulatory agency, again guided by scientific research, must not allow that established risk to be exceeded. This is the principle of the Delaney clause and for this reason the Delaney clause serves as a model for other environmental legislation.

[ATTACHMENT B]

HOW SAFE IS SAFE?—THE DESIGN OF POLICY ON DRUGS AND FOOD ADDITIVES

A CONSUMER'S VIEWPOINT

(By James S. Turner)

"How safe is safe?" is a misleading question for a conference on the design of policy on drugs and food additives. It implies the quest for an objective, scientific, if you will, standard of safety acceptable to all interested in the issue being considered. Unfortunately, in the real world today's acceptable standard of safety may be more or less acceptable than yesterday's or tomorrow's.

In addressing the problem of nuclear reactor safety, Dr. Alvin Weinberg, director of the Oak Ridge National Laboratory, puts the matter more precisely when he asks, "How safe is safe enough?" That is the question underlying the design of policy on drugs and food additives. It is not primarily a question for scientists; it is a policy question.

Dr. Weinberg spelled out the distinction effectively when he spoke at the dedication of the Paul B. Johnson Science Tower at the University of Southern Mississippi in January 1972:

> Many of the issues that arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the

> attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term trans-scientific for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science they are unanswerable by science; they transcend science. Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientist in contributing to the promulgation of such policy must be different than is his role when the issues can be unambiguously answered by science.

In conclusion Dr. Weinberg states:

> When what we [scientists] do transcends science and when it impinges on the public, we have no choice but to welcome the public—even encourage the public—to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate the will of the public and its representatives.

Safety as it has come to be used within the context of the food and drug laws and the complex of regulations supporting them is a trans-scientific problem. Under current laws a substance can be found safe only if it has passed through three phases of consideration. The nature of the safety problem may be better understood if it is examined within this context.

First is the objective, scientific determination of the discernible effects involved in the chemical's use. This determination is the responsibility of scientists.

Second is the judgment about which of these effects is a risk and which is a benefit. This judgment is ultimately made by the public, acting through its representatives and spokesmen or as individuals, but acting with a high degree of guidance from scientists, physicians, or other trained professionals.

Third is the decision that the agreed upon benefits of a given chemical exceed its agreed upon risks. This is a public, not a scientific, decision, made in public forums in which scientists act as equal, though in some cases better informed, participants with other segments of the public.

A safe chemical is one that has passed through all three phases satisfactorily. Its effects are known and agreed upon with some certainty by qualified scientists. The benefits and risks of the chemical have been sorted out accurately to the general satisfaction of the society. The society then has decided that the benefits of the use of the chemical in the way permitted outweigh its risks.

Unfortunately, this is not the way the determinations of chemical safety always work. Certain dramatic regulatory decisions during the past 20 years illustrate why the public increasingly doubts industrial, regulatory, and scientific assertions that the food and drug supplies are safe enough. The approval and then the subsequent banning of cyclamate, including the unnecessary references to the Delaney anticancer clause, illustrate the problems that occur when scientists cannot agree on the potential effects of a given chemical, but regulators act as if they do. The premature approval of the Salk polio vaccine and the subsequent 260 cases of vaccine-associated polio, 10 of which resulted in death, delineate the tragedy that can result when risks and benefits are improperly identified or weighed. The negligent release of certain lots of Sabin Type III oral polio vaccine and subsequent findings against the Government for that action suggest that the public is going to hold science and scientists to an increasing degree of responsibility for their decisions. Each of these events has a lesson which can be helpful in determining how safe is safe enough.

In 1963, the Division of Biologic Standards (DBS) of the National Institutes of Health, then the Nation's vaccine regulators, approved certain lots of Sabin Type III polio vaccine for use in a Philadelphia mass-immunization campaign. A Philadelphia housewife, who was 41 years old at the time, took a dose of one of the lots and contracted polio from the vaccine. She became a permanent quadriplegic.

After reviewing the case during 7 years of legal proceedings, the Federal district court in Philadelphia ruled that the vaccine lots had been released negligently by the DBS. It awarded damages of over $1 million to the injured party. Evidence showed that Government scientists responsible for protecting the public had kept shoddy, incomplete, or misleading records about vaccine safety. It showed that the statistical methods used to evaluate test findings were poorly constructed—so much so, in fact, that the presiding judge pointed to them as "* * * a perfect example of the old * * * chestnut, 'garbage in, garbage out.' "

Evidence introduced into the record suggested that when the mass-inoculation campaign was in the planning stages the Public Health Service's ad hoc polio advisory committee voted 6 to 4 to include a warning against the use of the Sabin Type III oral vaccine by adults. Subsequently the committee was informed by the manufacturer that "* * * the company must give serious consideration to the possibility that the type III vaccine will have to be withdrawn from commercial sale * * * if labeling precautions cannot be written with adequate safeguards that will not deter its sale * * *." Following this statement by the company the committee reversed itself, removing the warning about adults.

A careful examination of the regulatory records on Sabin polio vaccine revealed a nightmare of improper, mistaken, or negligent action—including a total lack of familiarity with the laws and regulations governing vaccine control on the part of the responsible officials—all taken in the name of and on behalf of science. The surprising reaction of officials faced with the responsibility for the $1 million judgment was to suggest that the regulations be changed so that their actions would become legal.

When the safety problem is viewed in this context the issues related to benefit and risk become less esoteric, abstract, and philosophical. The problem becomes a practical one. Mechanisms must be designed to ensure that the individuals charged with applying the available scientific knowledge to regulatory decisions have a proper sense of responsibility and a clear knowledge that they will be held accountable for their mistakes, as well as rewarded for their contributions. Until these mechanisms are developed, the public sense that the chemical environment is not safe enough will continue to grow. Unless the world of scientific decisionmaking on behalf of the public is opened to public scrutiny and evaluation, more and more policy restraints will be placed on the granting of responsibility to scientists. Alvin Weinberg puts the situation bluntly: "The republic of science can be destroyed more surely by withdrawal of public support for science than by intrusion of the public into its workings."

The Government's problem with certain lots of Sabin vaccine suggests how skeptical the public, through its trans-scientific institutions, is becoming of so-called scientific discretion. However, the Salk vaccine incident introduces another dimension. It suggests that the real safety problem involves not only a better weighing of benefits and risks, but the development of a better identification of benefits and risks.

The 260 victims of polio contracted from the Salk vaccine have often been the centerpiece in a number of theoretical discussions about risk-benefit. The trade-off is always between the number injured by the vaccine versus the number who would have been injured if the vaccine had not been used. H. V. Wyatt, in his article appearing in the January 26, 1973, issue of Nature, "Is Polio a Model for Consumer Research?," sums it up: "The situation, although regrettable, was certainly less severe than it might have been if the vaccine had not been used."

This is a comforting thought. But it lets science and the regulatory officials responsible for applying it off the hook too easily. If they had done their job properly the full benefit of the vaccine could have been had without the 260 casualties. This certainly would have been better than what occurred.

Dr. James Shannon said, in a 1966 address to the Oklahoma Frontiers of Science Foundation, that the Salk vaccine represented a scientific error. ". . . the decision of the Foundation—National Foundation for Infantile Paralysis—to throw its resources behind the development of an inactivated vaccine markedly increased the difficulties and greatly protracted the time required to develop the generally adopted polio vaccine we have today." The New York Times article reporting that speech states that "Dr. Shannon felt the 'error' of the National Foundation derived in part from the secrecy of its operations, which limited the input of external ideas."

Dr. Shannon's view is a retrospective one. It can be considered in future situations, but reasonable men could have disagreed about the choices when they were made in 1955. It is more difficult to accept the fact that in 1955 the bench scientists at the Division of Biologic Standards responsible for evaluating the safety of Salk vaccine refused free doses for their children. They did so because more than 6 months before the beginning of the Salk mass-immunization program three monkeys came down with what appeared to be a paralysis caused by the vaccine. This warning did not cause those responsible for the program to search out a potential problem, 6 months later, when the first five vaccine-related cases of polio were detected, a massive crisis program was undertaken to find and correct the problem. Within 30 days the reason for live polio contamination of the vaccine had been discovered, corrected, and the vaccine was back on the market.

In a program as important, sensitive, and dramatic as the Salk mass-immunization campaign, three sick monkeys should have been an effective early warning of the problems to come. That they were not suggests important weaknesses in the system for identifying risks and benefits which must be corrected before the weighing of benefits and risks can be seriously undertaken.

The manipulation of science to make risks appear more acceptable, illustrated by the *Philadelphia Sabin* case, and the failure of science to detect warnings, as in the *Salk* case, feed public skepticism about claims that all is well with food and drugs. This skepticism, shared by a good number of scientists, underlies the strong support for the Delaney anticancer clause of the food and drug law, which prohibits the use in human foods of any chemical which has caused cancer when ingested by man or animal.

In October 1969, the Secretary of Health, Education, and Welfare removed cyclamate from the list of food chemicals generally recognized as safe, better known as the GRAS list. He removed the chemical not because scientists agreed that it was unsafe, but because it could no longer be said that scientists agreed that it was safe. A number of observations contributed to this doubt concerning cyclamate. It produced a human metabolite which caused genetic damage in rats. It and the metabolite caused teratogenic damage in chickens. It bound itself to plasma, thus inhibiting drug delivery to the body. It inhibited the effect of vitamin K. It had caused some unreported cancerous tumors in 1950 FDA tests. When combined with saccharin, it had caused cancer in rats.

For apparently political reasons the Secretary made unnecessary references to the Delaney anticancer clause to justify removal of the chemical from the GRAS list. The clause reads as follows: "*Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *."

It was unnecessary even to refer to the clause in banning cyclamate because once safety became a question, the chemical could not be used unless it had been tested and shown to be safe. This meant that its effects had to be demonstrated, that its benefits and risks had to be sorted out and then weighed. If qualified scientists had found during this period that the chemical did cause cancer when ingested by man or animal, then the Delaney clause could have been invoked. The previously made public determination that the potential risk of including a cancer-causing chemical in the food supply outweighs any benefits that the chemical might have would then have controlled the situation. If this procedure, as outlined in the law, had been followed, the importance of the Delaney clause could have been more accurately assessed and appreciated. Instead, the premature reference to the clause led to a widespread misunderstanding of the purpose and principle underlying it.

The principle of the Delaney clause is that weighing of benefits and risks is not a purely scientific question; it is a policy question that requires an informed public decision. The principle of the Delaney clause is that the weighing of benefits and risks is not the sole province of a regulatory agency or its scientific advisers. The Delaney clause applies this principle to those chemicals which cause cancer when ingested by man or animal. It does this on the advice of a large segment of the scientific community which argues that the effects of even traces of a cancer-causing substance cannot be predicted. Relying on this advice the public had adopted the policy that no benefit is worth the possible hazard of adding a cancer-causing chemical to the food supply. The clause rests on scientific discretion. Scientists—and scientists alone—make the determination that an ingested chemical has caused cancer. The clause rests on the accepted operating principle that there is some relationship between the effects of the chemical on animals and its effects on man. This is the principle that allows drugs and food additives to be shown safe and to be marketed. The clause avoids the demand of absolute safety. Instead it says that in relation to the cancer risk the food supply will be safe enough only if no additional cancer-causing chemicals are added to it.

The Delaney clause can certainly be improved, but the central principle on which it rests must be kept intact. Safety is a policy question which demands the weighing of properly identified risks and benefits by the public. It is not an objective, scientific determination. The weighing mechanism can be improved, but improvement will not be accomplished by giving regulatory authorities more bureaucratic discretion. The Delaney clause, unlike any other section of the Food, Drug, and Cosmetic Act, recognizes and is premised upon the limitations of science.

The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health stated the limitation on proving food chemical safety. The panel said, "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods." As a member of the panel I concurred with that statement. It appeared to me to be a warning. Since science could never be sure of a chemical's safety, it seemed obvious that as a matter of policy we should be cautious in allowing the use of chemicals in food. Unfortunately, many individuals both inside and outside of science took this statement to mean the opposite. Since safety cannot ever be proven conclusively, they argued, we ought to be cautious in restricting the use of chemicals. It is this attitude against which public sentiment is reacting.

Increasingly scientific evidence relates various chemicals to serious problems of human health. Responsible scientists have suggested that some chemicals may contribute to the development of certain kinds of mental retardation, 95 percent of which is of unknown origin. A large portion of the cancer research community spends its time evaluating the capability of various chemicals to cause cancer, although the cause is yet to be found. Some geneticists suggest that chemicals used in foods and drugs might play an important role in causing much of the society's genetic and mutagenic damage. For example, 20 to 30 percent of American pregnancies end in spontaneous abortion, stillbirth, or deformity.

Scientific research has identified a number of serious health problems for which the causes are at best elusive. It has also generated enough evidence to suggest a possible relationship between these disease conditions and the growing use of a number of chemicals in the drug and food supply. Diseases of unknown origin and chemicals with suspicious side effects combine to raise questions of drug and food additive safety and policy to a high level of public concern.

Increasingly pointed public questions are being raised about assumptions underlying chemical regulation. Dr. Jacqueline Verrett and Jean Carper, both of whom played an important role in the cyclamate ban, ask these in their book to be published in 1974 by Simon & Schuster, Eating Can Be Hazardous to Your Health:

> When industry tosses around the term benefit-risk, what do they mean? Do they mean consumer health benefits weighed against consumer health risks? Or consumer economic benefit against consumer health risk? Or some kind of consumer social benefit, such as time saving, against consumer health risk? Or, on the other hand, do they mean industry economic benefit against consumer health risk?

My experience is that industry means all of these. This fact, too, raises the level of public concern about drug and food additive safety and policy.

The point of all this is that the safety of drugs and food additives as a function of the weighing of benefits and risks is not what the public concern is all about. The real problem is twofold. The effects of chemicals in food and drugs have not yet been determined satisfactorily. No generally accepted definition of benefits and risks has been agreed upon. It is on these two problems that from the consumer's point of view the attention of science should be focused.

[ATTACHMENT C]

CONSUMER VIEWS OF THE DELANEY AMENDMENT

(By James S. Turner)

OBJECTIVE

This paper describes the authors view of: the views and interpretations of the contemporary consumer movement with regard to the Delaney anticancer clauses of the Federal Food, Drug, and Cosmetic Act, its rationale; possible alternatives; and consumer interpretation of and reaction to recent public critiques of the clause.

THE DELANEY ANTICANCER CLAUSES OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. 321 ET SEQ.

1. 409(c)(3)(A) provided . . . That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this provision shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subjected (f) and (g) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal;

2. 706(b)(5)(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary

to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive if after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided*, That clause (i) or this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

3. 512(d)(1)(H) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that—

> * * * such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals; * * *

he shall issue an order refusing to approve the application.

SUMMARY

> Consumption is the sole end and purpose of all production; and the interest of the producer ought to be attended to only so far as it advances that of the consumer.
>
> But in the mercantile system, the interest of the consumer is almost constantly sacrificed to that of the producer; and it seems to consider production, and not consumption, as the ultimate end and object of all industry and commerce.
>
> —Adam Smith, "The Wealth of Nations," third edition 1784.

Organized consumer groups, consumer advocates, and consumer spokesmen place the health and welfare of the individual consumer at the center of the controversy about whether cancer-causing chemicals should be allowed in the food supply. They believe that opponents of the Delaney anticancer clauses—which prohibit from the food supply chemicals which cause cancer when fed to animals or men—are primarily concerned with the well-being of food and chemical producers and only secondarily concerned with the health and well-being of individual consumers.

Specifically, growing indications of potential hazards to the individual consumer which might be related to environmental chemicals, has led to consumer support for the Delaney clauses type of restrictions on chemicals in foods which have not been shown to be safe. For example, cancer is a major cause of human death for which no generalized cause has been identified but which some experimentation and some experience relates to the ingestion of chemicals. Birth defects occurring at an alarming rate (1 in every 14 births involves a defect according to the March of Dimes), are largely of unknown origin, and have been related to environmental chemicals by both research and experience. Genetic damage which can be inherited from one generation to the next, also has been related to environmental chemicals.

The President's Science Advisory Committee Panel on Chemicals and Health stated the situation succinctly in its 1974 report:

> The very absence of these former sources (common infectious diseases and nutritional diseases) has left the field clear for the chronic degenerative diseases, some of which are likely to have external chemical causes. We need now to develop ways to deal with these slower acting and less direct causes of death and chronic sickness.

The loose collection or organizations and individuals generally called the "consumer movement" in the United States tend to believe that the principle of social policy embodied in the Delaney clause is the best way to deal with these slower acting and less direct causes of death and chronic sickness. In general, they are also highly skeptical that any better principle for dealing with the chemical threat to man can be found. Since the time between coming in contact with a dangerous environmental chemical and recognizing the injury, its causes may be 20 or more years, consumer defenders of the Delaney clause principles, argue that waiting until human injury is obvious will unnecessarily condemn millions of individuals to death or disability.

The argument on behalf of the Delaney clauses rests on making a distinction between its public aspects and its scientific aspects. When this distinction is made, the controversy over the Delany clauses forms into two related but distinct issues. One, should chemicals known to cause cancer be allowed in human food? Two, how do we determine which chemicals cause cancer?

There is really little debate about issue No. 1. Everyone seems to agree that cancer-causing chemicals should be kept out of food. Dr. Phillip Handler, president of the National Academy of Sciences, hosted a May 15, 1973, Academy Forum on the "Design of Policy on Drugs and Food Additives." In his concluding summary after a day-long discussion which often touched on the Delaney clauses, Dr. Handler said:

> Certainly, on its face, all other things being equal, it (the Delaney clause) is a perfectly rationale guide to desirable social behavior. No one in his right mind wants to put carcinogens into anything intended for human consumption.

In spite of its apparent reasonableness and rationality, the Delaney clauses continue to be the recipient of vigorous attack. Bernard L. Oser, Ph. D., who has been responsible for testing many food additives as a private contractor to industry and Government, wrote in the August 13, 1973, issue of Chemical Engineering News:

> In these days of increasing need to expand and preserve food supplies, to develop new sources of nutrients and to improve acceptability, pragmatic considerations justify the removal of unreasonably restrictive regulations founded on hypothetical hazards implicit in the present interpretation of the Delaney Clause.

Consumer defenders of the Delaney clauses view such attacks as arguments made on behalf of food and food chemical producers, and to the detriment of consumer safety and health. The charge that the clause is unscientific is defended against by pointing to the large number of scientists, including researchers at the National Cancer Institute, who support it. The belief that only scientists should determine the benefit/risk for chemicals used in food is countered by the argument of pro-Delaney advocates that determining how much risk the public should bear is a public policy issue not primarily a scientific issue.

At the heart of the Delaney controversy is how public policy should be set when the experts are at odds over the meaning of the scientific facts which underly the policy. Consumer defenders of the Delaney clauses argue that since they know so little about the nature of cancer and are at constant odds about the meaning of their research on cancer, the caution built into the Delaney clauses principle is the best policy.

INTRODUCTION [1]

"How safe is safe enough?" is the question central to regulation of food additives in the American food supply in general and evaluation of the Delaney anticancer clauses in particular. This question is not primarily a question for scientists; it is a policy question to be answered by society through its chosen representatives.

Dr. Alvin Weinberg formerly Director of the Oak Ridge National Laboratory spelled out the distinction between the question of science and the question of public policy in his address at the dedication of the Paul B. Johnson Science Tower at the University of Southern Mississippi in January, 1972:

> Many of the issues that arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term trans-scientific for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science. Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientist in contributing to the promulgation of such policy must be different than is his role when the issues can be unambiguously answered by science.

In conclusion Dr. Weinberg states:

> When what we [scientists] do transcends science and when it impinges on the public, we have no choice but to welcome the public—even encourage the public—to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate to the will of the public and its representatives.

The principle of the Delaney clauses is that weighing of benefits and risks is not a purely scientific question; it is a policy question that requires an informed public decision. The principle of the Delaney clauses is that the weighing of benefits and risks is not the sole province of a regulatory agency or its scientific advisors.

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[1] The introduction is adapted from an address delivered by the author at the May 15, 1973, Academy Forum of the National Academy of Sciences entitled "How Safe Is Safe? The Design of Policy on Drugs and Food Additives." (The proceedings of the Forum are about to be published.)

The Delaney clauses apply this principle to those chemicals which cause cancer when ingested by man or animals. On the advice of a large segment of the scientific community, they exclude such chemicals from the food supply because the effects of even traces of a cancer-causing substance cannot be predicted. Relying on scientific advice the public, acting through Congress, has adopted the policy that no benefit currently known to man is worth the possible hazard of adding a cancer-causing substance to food.

Scientists—and scientists alone—make the determination that an ingested chemical has caused cancer. The Delaney clause rests on the accepted operating principle that there is some relationship between the effects of a cancer-causing chemical on animals and its effects on man. This is the principle that allows drugs and food additives to be marketed to men after tests show them to be safe for animals. The clause does not demand absolute safety. Rather, it demands that no additional cancer-causing chemicals be added to the food supply.

Consumer defenders of the Delaney clauses argue that their central principle must be kept intact. Safety is a policy question which demands the weighing of properly identified risks and benefits by the public. Safety is not the result of solely an objective, scientific determination. It also involves a matter of opinion. The mechanism for sorting and weighing opinion and fact can be improved but not by giving regulatory authorities more bureaucratic discretion.

Pure scientific knowledge, alone and unaided by commonsense and doubting public questions, is a weak reed on which to rest the entire future and well-being of the American public. The imperfect science of a regulatory agency is even less suited to be the repository of unrestricted confidence that the well-being of individual consumers will be its sole objective. The Delaney clauses recognize the imperfections and limitations inherent in science and in regulatory agencies.

Safety, as it has come to be used within the context of the food and drug laws and the complex of regulations supporting them, is a trans-scientific (in Weinberger's words) problem. A "safe" chemical is one that has passed through three phases of consideration satisfactorily and is approved for use. Its effects are known and agreed upon with some certainty by qualified scientists. The benefits and risks of the chemical have been sorted out accurately to the general satisfaction of the society. The society has decided that the benefits of the use of the chemical in the way permitted, outweigh the risks. The Delaney clauses are society's determination that cancer-causing chemicals pose such a potential risk that they should not be added to food whatever their alleged benefit.

In the Delaney clauses, the American society has recognized both the limitations of science and public role in defining acceptable risks. The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health stated the limitation on proving food chemical safety. The Panel said, "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods."

This observation can be taken two ways. It can be a warning. Since science could never be sure of a chemical's safety, it seems obvious that as a matter of policy we should be cautious in allowing the use of chemicals in foods. Unfortunately many individuals, both scientists and nonscientists, take this statement to be the opposite of a warning. Since safety cannot ever be proven conclusively, they argue, we ought to be cautious in restricting the use of chemicals. It is against this argument that the Delaney clause has been constructed and against which consumer defenders of the Delaney clause are reacting.

The following sections of this paper attempt to explore three aspects of consumer attitudes of the Delaney clauses. First, the scientific opinion, which consumer defenders of the Delaney clauses believe provide a sound basis for support of the clause, is presented. Second, some consumer attitudes on the policy aspects of the clauses are outlined. Third, some suggestions, proposals, and expectations concerning supplements, explanations, and applications of the Delaney clauses are outlined.

I. THE SCIENTIFIC BASIS OF THE DELANEY CLAUSES

The most recent scientific consideration of the Delaney clauses appear in Chemicals and Health the September 1973 report of the Panel on Chemicals and Health of the President's Science Advisory Committee. It focuses on and describes the major dispute with the Delaney clauses expressed by its critics—its zero tolerance of cancer-causing chemicals.

"A 'no-detectable amount' clause," the Panel states, "is a refuge in the face of ignorance. Was mature scientific knowledge presently available regarding dose response relationships and extrapolation to man, the problem of carcinogenicity could be dealt with (in) a scientifically rational manner." The clauses are currently necessary, the report suggests, because of lack of detailed knowledge telling how little of a carcinogen will be harmful when ingested.

On two additional occasions in the report the Panel talks of the lack of scientific information surrounding carcinogens, the lack of discretion allowed to the administrators of the food and drug law by the clause and makes the allegation that the clause limits scientific direction.

> When considering a decision and faced with incomplete and insufficient information, the administrative and legislative processes tend strongly to the side of a conservative prudence in the name of health. There are several notable example which Congress has replaced with scientific discretion by statutory mandates to "protect" human health inflexibility. The Delaney clause to the Food, Drug and Cosmetic Act is probably the best known.
>
> In some cases, the Congress has clearly assumed the role of judge of social issues concerning how safe is safe enough. The amendment to the Food, Drug and Cosmetic Act which determines the destiny of food additives found to be carcinogenic in animals or man (Delaney amendment) is perhaps the best known example * * *. It is interesting to note that it seems to be the very lack of sufficient information plus an implied threat in each case which has led Congress to take social judgment making into their own hands.

It is interesting to note that though the language is colored in a way to suggest dissatisfaction with the Delaney clauses, the President's Panel comes out on the side of retaining the Delaney clause as they are because of the continuing lack of the information needed to do anything else. The Panel report supports the consumer advocates of the Delaney clauses using the very same arguments which brought the clauses into being originally and which has sustained for retaining the clauses. Arthur Flemming, then Secretary of Health, Education, and Welfare, testified twice for the clause in 1960 when it was extended to cover color additives. His comments are somewhat long but they spell out in detail what has become, over the last decade and one-half, the position of the Delaney clauses proponents.

The Department's position is that the proposed color additive legislation should include an anticancer clause that makes illegal the use of any color that will induce cancer when tested by appropriate methods. We believe this position to be the only sound public policy in view of the fact that our experts tell us present scientific techniques do not permit them to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.

The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for a man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstading of how this provision works. It allows the Department and the scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen

So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound. (Statement by Hon. Arthur S. Flemming, Secretary of Health, Education and Welfare before the House Committee on Interstate and Foreign Commerce, May 9, 1960.) House Report No. 1761 to accompany H.R. 7624, 86th Congress, 2d Session, p. 14.

Secretary Flemming left the door open for the future in his testimony before the House Committee:

Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. . . . House Report No. 1761 to accompany H.R. 7624, 86th Congress, 2d Session.

The only point that seems to offer the possibility of controversy is the anticancer clause. Secretary Flemming has made a very strong case for it in his testimony before the House Committee. This is grounded on the scientific fact of life that no one, at this time, can tell us how to establish a safe tolerance for a cancer producing agent. No one knows how much or how little of a substance which produces cancer in test animals is needed to cause cancer in man, or when the cancer may develop. Until cancer research makes a breakthrough at this point, there is no scientific basis on which discretion could be exercised in tolerating a small amount of a known carcinogen, either in food, drugs, or in cosmetics. When and if science can assure us that a safe tolerance can be established, the Department will ask the Congress to modify the anti-cancer clause.

In discussing the practical operation of the anti-cancer clause, Secretary Flemming said:

Some of the opposition to inclusion of an anti-cancer provision . . . arises out of a misunderstanding of how this provision works. . . .

It has been suggested that once a chemical is shown to induce a tumor in a single rat, this forecloses further research and forever forbids the use of the chemical in food. This is not true. The conclusion that an additive "is found to induce cancer when ingested by man or animal" is a scientific one. The conclusion is reached by competent scientists using widely accepted scientific testing methods and critical judgment. An isolated and inexplicable tumor would not be a basis for concluding that the test substance produces cancer.

It has also been suggested that when a compound shown to produce cancer in test animals has been modified in chemical structure so that it no longer produces cancer, it continues to be incriminated by its past history. This, too, is erroneous. The Food and Drug Administration would—and should—take a close look at the modified compound to be certain that it did not have the same cancer potential as its parent. But once convinced that the cancer potential had been eliminated, the anticancer clause would not preclude use of the substance.

Finally, doubt has been expressed about the authority of the Department to reverse a decision in this area. This, of course, is an unfounded doubt. When new evidence is presented the Department has not only the right, but the obligation to evaluate this evidence and determine whether a previous decision should be reversed.

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance," "From Bellyache to Headache—Is the Color Additives Bill the Remedy?" William W. Goodrich, Assistant General Counsel for Food and Drugs, United States Department of Health, Education, and Welfare, Washington, D.C., delivered at a meeting of the Legislative Section, Pharmaceutical Manufacturers' Association, Boca Raton, Florida, Thursday, February 4, 1960.—All the quoted material is from Toulman, "Treaties of Food and Drug Law," 1963 edition, pp. 909–911.

While this diversion into the original testimony of Secretary Flemming is long it is valuable because it forms the basis of current consumer support for the existing Delaney clause. In addition, it demonstrates that the problems discussed by the 1973 Presidential Panel on Chemicals and Health are not new and suggest why that Panel ended up supporting the Delaney clause even though it probably would rather not have.

In 1970, the Surgeon General of the United States, faced with a continuing restiveness with the Delaney clauses on the part of food chemical manufacturers and parts of the scientific community, gathered a special ad hoc committee of cancer experts to help him address the problem. After reviewing the Delaney clauses and the threat of environmental carcinogens, the ad hoc committee quoted extensively from the 1960 tesimony of Secretary Flemming. The committee then said, "the scientific basis on which the Governments' position was established in 1960 remains valid. The progress of knowledge in carcinogenesis in the last decade has only strengthened the points made in Secretary Flemming's testimony." [2]

There has been a tendency to go back and forth about the Delaney clauses for its entire existence. Specifically, from its inception, an argument has raged about whether the Food and Drug Commissioner should have the authority to set tolerances for cancer-causing substances. The scientific arguments of Secretary Flemming in 1960 reiterated a decade later by the ad hoc committee of the Surgeon General were directed at the belief expressed by some individuals that such authority should be granted to the Commissioner.

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[2] The full report of the ASK Committee is entitled "Evaluations of Environmental Carcinogens." It is called the "Report of the Surgeon General, USPHS Apr. 22, 1970, Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens," National Cancer Institute, Bethesda, Md. 20014. Requests for reprints of the entire report should be sent to Dr. John A. Cooper, Building 37/3A07 National Cancer Institute. The report has also been reprinted at pp. 180 to 198 of the Senate hearing "Chemicals and the Future of Man" before the Subcommittee on Executive Reorganization and Government Research, Apr. 6–7, 1971.

Secretary Flemming relied on an earlier report from the National Institutes of Health which concluded "that there is at present no sure way to determine how much or how little of a carcinogen is necessary to produce cancer in a human being, how long it would take for a cancer to develop or how to control levels of ingestion or exposure where more than one source of exposure is likely." The quotation is from Toulman, "Treatise on Food and Drug Law" and reports the conclusions of the report on "The Role of Certain Chemical and Physical Agents in the Causation of Cancers." [3]

In 1970, the Surgeon General's ad hoc committee felt it necessary to once again knock down assertions that seemed to imply that safe levels of a carcinogen could be established. "It is essential to recognize," the committee reported, "that no level of exposure to a carcinogenic substance, however low it might be, can be established to be a 'safe level' for man . . . The current legislation in the field of food additives, with its anticancer clause, is based on this principle."

The attack on the requirements of zero-tolerance for cancer-causing substances in food has been the central thrust of anti-Delaney clauses spokesman. However, repeated the scientists most directly concerned with cancer research have affirmed that they are unable to say at what level a cancer-causing substance becomes safe and therefore have supported the Delaney clauses. This support from the scientific community has been the main scientific argument used by consumer advocates of the Delaney clauses.

A second but less persistent argument, which has been turned to more frequently as the zero-tolerance argument has met persistent scientific opposition, is the one-most-irrelevant-test argument. This argument appears to be based on both the theory and effect of the Delaney clauses. The more unsophisticated presentation of the argument is that if one mouse is given massive doses of a chemical and the mouse contracts cancer, then the chemical is forever banned from food use thereby depriving the food industry and the public of a potentially useful chemical and discouraging research into the chemical. It was this argument that Secretary Flemming attempted to defeat when he pointed out that "the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and the scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining the safe threshold dose for the established carcinogens."

Thus, only if tests involved, of however many mice at whatever levels, show that the chemical is a cancer-causing chemical is the act engaged. Thus, if a test is considered to be irrelevant by the scientific community or it showed that if an intervening event, not the chemical, caused cancer, then the Delaney clause would not be engaged.

Unfortunately, the misunderstanding about the way in which the Delaney clauses work have persisted, in spite of repeated arguments and legal action making explicit what Secretary Flemming testified to. (Incidentally, his testimony, as the major part of the legislative, history of the clauses forms the most significant guide to what Congress meant when it adopted the clauses and thus has important legal force of its own.) Even the prestigious Presidential Panel on Chemicals in Health repeated a very sophisticated form of the argument.

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[3] G. Burroughs Mider, M.D., Associate Director in Charge of Research, National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health, Education, and Welfare, prepared at the request of the Secretary of Health, Education, and Welfare as part of his testimony before the Committee on Interstate and Foreign Commerce, House of Representatives, 86th Cong., 2d session, on H.R. 7624 and S. 2197, Jan. 26, 1960, hearings Jan. 26, 27, 29, Feb. 10, 11, Mar. 11, Apr. 5, 6, and May 9, 1960, p. 45.

On page 121 of its report, the Panel said, "It can be argued that as additional understanding accumulates as to biological mechanisms underlying neoplastic disease, and as one obtains more detailed information on how chemicals interact with biological issues, the Delaney clause may well be modified." On page 11, the panel says "once he (the Commissioner applying the Delaney clauses) acts, almost all motivation to study either benefits or risks further is gone, thus keeping us from ever learning more about what should have been done." Together, these two arguments represent a statement of the misunderstanding about the Delaney clauses which Secretary Flemming addressed in 1960.

On January 15, 1973, the New York Academy of Sciences held a symposium on the Delaney clauses. The transcript of the meeting is still in the process of being edited for publication. However, the consensus of scientists present was clear and reported by the press. In the January 22, 1973, edition of Food Chemical News they reported that "The overriding consensus was that change should not be made (in the Delaney clauses) because there is yet no scientific basis for setting a tolerance for carcinogens in the food supply . . . the formal presentations included several views of the cancer mechanism, ranging from the single molecule theory of cancer causation to interference with the complicated enzyme system of humans and animals."

It was suggested during the meeting that it was demonstrated by accepted scientific procedures, that if during an animal feeding, testing for cancer, if it appeared in a significant amount in the animals but that a separate cause for the cancer distinct from the chemical was the reason for the cancer, the Delaney clause would not apply. Thus if the peculiar enzymatic action of the test in animals caused the cancer or if a dose related toxic precondition such as cirrhosis of the liver had to be present for the cancer to occur and the chemical was shown not to be the cause of the cancer, then the Delaney clauses would not apply. This would result from the fact that scientists agreed that the chemicals were not the cancer-causing agent.

On April 27, 1973, the FDA proposed a food additive regulation (in the Federal Register of that date), with regard to selenium, a nutrient for addition to animal feed which explained and endorsed the theory of the clauses outlined during the January 15 meeting of scientists. It would seem reasonable that if the cancer-causing effect of a metabolic situation rests on the need for the existence of a toxic effect which is agreed upon by scientists to be dose related, that chemical is not a carcinogen and that therefore the Delaney clauses do not apply. Whether it should apply or not is a separate question. The FDA explanation of the interpretation of the Delaney clauses in this situation is long but nonetheless, is of enough importance to be included in its entirety:

> 5. The applicability of the anticancer clause (sec. 409(c)(3)(A)) of the act to the addition of selenium to animal feed has been thoroughly considered because of the questions that have been raised concerning the possible carcino-

> genic activity of selenium. Available data have been evaluated by the Food and Drug Administration and the National Cancer Institute. Based on these evaluations, it has been concluded that the judicious administration of selenium derivatives to domestic animals would not constitute a carcinogenic risk. In three of the six studies available on the subject, test animals were found to have developed neoplastic lesions. These lesions were concluded to be a consequence of the liver cirrhosis produced by frank selenium toxicity. Further evaluation of the results of these three studies was complicated by the unusually high levels of selenium that had been administered, faulty experimental design, and/or infectious conditions present in the animal colonies used. Results of the remaining three studies, all of which were well controlled investigations, were negative for carcinogenic activity.
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> Selenium at high dietary levels (above 2 p/m for experimental animals) is a proven hepatotoxic agent. Early studies at dietary levels of 5, 7, and 10 p/m showed liver damage and regeneration in rats and an increased incidence of hepatoma in treated animals as compared with controls. Hepatoma did not occur in the absence of severe hepatotoxic phenomena. In more recent studies, hepatotoxicity was observed in rats fed selenium at 2 p/m. At 16 p/m more severe liver damage was observed but was not associated with hepatoma. No hepatotoxic effects were noted at 0.5 p/m or below.
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> In this respect, selenium is no different from a number of foods and drugs available in the marketplace today. Beverage alcohol, for example, is associated with a higher incidence of liver cirrhosis, which, in turn, is associated with a higher incidence of liver cancer. Other common agents, at high levels, may produce the same result.
>
> The Commissioner is of the opinion that these foods and drugs are not, by reason of their capacity to induce liver damage when abused by being consumed at high levels, properly classified as carcinogenic because of their potential association with a higher rate of liver cancer. The various anticancer clauses contained in the act (secs. 409(c)(3)(A), 512(d)(1)(H), 706(b)(5)(B), 72 Stat. 1786, 82 Stat. 345, 74 Stat. 400; 21 U.S.C. 348(c)(3)(A), 360b(d)(1)(H), 376(b)(5)(B)) were predicated on the theory that, since we do not know the mechanisms of carcinogenesis, even one molecule of a carcinogen should not be allowed into the food supply. The anticancer clauses do not apply in the case of an agent that (1) occurs naturally in practically all foods, (2) is used in a manner such that the natural level in food is not increased, (3) has a definite hepatotoxic effect/no-effect level, and (4) has a possible carcinogenic effect which is associated only with the hepatotoxic effect.
>
> Accordingly, the Commissioner has concluded that: (1) The available information does not support classification of selenium or its compounds as having carcinogenic activity, (2) the use of selenium as set forth below constitutes no carcinogenic risk, and (3) the limitations set forth below, while satisfying the animals' dietary need for selenium, will assure safety to animals treated with sodium selenite or sodium selenate and to consumers of edible products of such treated animals. 38 F.R. 10459—10460 (Apr. 27, 1973).

Thus, it can be seen that the belief of the President's Panel that as "additional understanding accumulates as to biological mechanism underlying neoplatic disease * * * the Delaney clauses may well be modified" is not necessary to joining the reasoned progress of science with the legal restraint of the Delaney clauses. Indeed, the Delaney clauses, under close scrutiny, turn out to a singularly well-constructed piece of social legislation.

Properly understood, the Delaney clauses not only do not inhibit scientific research, as the Panel suggested, but they actually encourage it. Under the Delaney clauses, animal tests which ended with significant amounts of cancer in their test groups would have two possible interpretations. One, that the chemical caused the cancer. The other, that some other intervening dose-related toxic event caused the cancer. It would seem that with this possibility, existent researchers would jump at the chance to discover which group their chemical fell into.

Incidentally, one of the strongest defenders of the Delaney clauses, and an outspoken scientific critic of the FDA, for its inadequate regulation of nitrates in food, Dr. William Lijinsky believes that: "The present use of selenium compounds in animal feeds should not pose a legal dilemma." "The object," he says, "is to raise the nutritional status of those animals on selenium-deficient diets to that of animals on diets with normal selenium content. "Analysis of the meat of such animals would show no abnormal residue of selenium."[4] Dr. Lijinsky does not believe that selenium is a carcinogen because of conflicting, incomplete, and inadequate test results.

The Presidential Panel evidenced another misunderstanding about the working of the Delaney clauses when it commented on the removal of cyclamate from the marketplace. The Panel said on page 106 of its report:

> On October 12, 1969, a leading producer provided evidence to the FDA that cyclamate had caused cancer in animals. It seems highly likely that even if no Delaney provision in the law existed and no FDA edict had been issued, that any responsible producer of ethical pharmaceuticals would have taken action to limit the use of cyclamates or perhaps even to withdraw them.

This observation implies that the Delaney clauses were relied upon by HEW to remove cyclamates from the marketplace. This was not the case. It also implies that but for the Delaney clauses, the FDA would have no authority to remove cyclamates from the marketplace. This also is erroneous. Actually, the FDA removed cyclamate from its list of food chemicals, generally recognized as safe under the authority of the 1958 Food Additive Amendments of which the Delaney clause is only one small section.[5]

Under the food additive amendments, only those chemicals which are either generally recognized as safe or proven safe and granted food additive status can be added to food. Given the current lack of scientific knowledge about the likelihood of harm from low levels of cancer-causing chemicals, no chemical which causes cancer in animals can be added to food irrespective of whether the Delaney clauses are a part of the act or not. In a very broad sense, the Delaney clauses are a legal redundancy. It is not an administrative redundancy, however, since often actions are taken for reasons which lie outside the workings of the Delaney clauses but are explained to the public as if they were mandated by the Delaney clauses.[6]

On May 15, 1973, the National Academy of Sciences held an Academy Forum on food additive and drug regulation. During that symposium, Peter Hutt, the Assistant General Councel of HEW for the Food and Drug Administration, explained the working of the Delaney clauses. He pointed out that on only two occasions, both involving obscure packaging ingredients, had the Delaney clauses been invoked as a legal justification for agency action.

Commenting on the Delaney clauses in his closing summary of the May 15, 1973, National Academy of Sciences Forum, Academy president, Dr. Phillip Handler, himself a sometime critic of the clauses, made a number of important observations about the clauses:

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[4] Senate Select Committee on Nutrition and Human Needs, hearing on food additives, Sept. 21, 1972. pt. 4C, p. 1669.

[5] See Turner, Vanderbilt Law Review, October 1971, "The Delaney Anticancer Clause: A Model Environmental Protection Law."

[6] See the "Chemical Feast" by James S. Turner, ch. 1, and p. 250 footnote for a detailed account of the legal implications of the banning of cyclamates.

> Mr. Hutt told us that, point of fact, the Delaney clause has been invoked only two times. I share Mr. Snodgrass' surprise that it had not been invoked in the case of cyclamates. This may be taken as a demonstration of our communicative failure; evidently we need many other forums and places in which to talk and attempt to reduce our misunderstandings.
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> . . . The Delaney clause was discussed in several ways . . . For my part, I began to view that clause as a great red herring rather than as a problem in our society. Certainly, on its face, all other things being equal, it is a perfectly rational guide to desirable social behavior. No one in his right mind would want to put carcinogens into anything intended for human consumption. We should be perfectly willing to accept that guideline until the day when we find ourselves in the position of banning as a carcinogen some chemical entity which also offers great benefit. Until that time comes, we will not have to test the validity of the Delaney principle. When it does come, we will have no recourse but to test the validity of the principle in a real live situation.
>
> Meanwhile, talking about a problem that is nonexistent in reality doesn't serve our purposes particularly well. It has been said that the great harm of the Delaney clauses is its deterrence to those who might otherwise be exploring new and important food additives. No such real case in point is known to me. I agree that one must be troubled by a law that in effect seems to say: "Since compound X has been shown to be tumorigenic in high doses, go no further; do not look at the lower end of the dose-response curve, regardless of benefit." Such a situation seems, to me, to be repugnant. But the time to address it will be the day when a real test case is before us.

Thus Dr. Handler, viewed by consumer advocates supporting the Delaney clauses as an opponent because of previous attacks on the clauses, comes out at nearly the same point as Anita Johnson, staff attorney of the Ralph Nader supported health research group and one of the staunchest and most articulate of the consumer advocates of the Delaney clauses. In her publication, "Cancer Prevention and the Delaney Clause" she wrote:

> If a carcinogenic food additive is thought to be so crucial to civilization that it is worth possibly great cancer risk, Congress can be approached for an exemption for that individual additive.

Dr. Handler and Anita Johnson both conclude that the Delaney clauses should remain intact until a difficult case presents itself and then the issue can be raised with Congress in the context of that case.

II. THE SOCIAL PUBLIC POLICY DIMENSIONS TO THE DELANEY CLAUSES

The scientific principle of the Delaney clauses is that since the effects of low doses of known cancer causing chemicals are unknown, none should be added to food. The public policy principle underlying the Delaney clauses is that Congress should grant administrative discretion to regulatory agencies only when enough clear, sound scientific, or technical data exists to make the proper exercises of the discretion likely.

The special ad hoc committee of the Surgeon General addressed the meaning of and distinction between these principles in its "Evaluation of Environmental Carcinogens:"

> It is impossible to establish any absolutely safe level of exposure to a carcinogen for man. The concept of "toxicologically insiginificant" levels (as advanced by the Food Protection Committee of the NAS/NRC in 1969); of dubious merit in any life science, has absolutely no validity in the field of carcinogenesis. Society must be willing to accept some finite risk as the price of using any carcinogenic material in whatever quantity. The best that science can do is to estimate the upper probability limit of that risk. For this reason, the concept of

> "safe level for man", as applied to carcinogenic agents, should be replaced by that of a "socially acceptable level of risk."
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> While science can provide quantitative information regarding maximum risk levels, the task of ultimately selecting socially acceptable levels of human risk rests with society and its political leaders. The evaluation of the balance of benefits and risks, required for such a decision by society, should not be the result of uninformed guesswork but should be reached on the basis of complete and pertinent data, social as well as scientific. It is necessary therefore, to define the extent of arbitrariness and uncertainty existent in the processes of interpreting animal response data and subsequently extrapolating them to man. The principle of zero tolerance should be applied in all but the most extraordinary of cases.[7]

At the 140th meeting of the American Association for the Advancement of Science held in San Francisco in February 1974, Dr. Alexander M. Schmidt, Commissioner of the FDA echoed the sentiments of the ad hoc committee. He termed the Delaney clauses a "legitimate legislative expression of society's increasing concern with technologic advances in the food industry and its reluctance to accept less than absolute safety in the food supply." He went on to say:

> . . . (W)hile detection methods increase in sensitivity, the ability of scientists to relate these findings to human health are not keeping pace . . .
>
> The more practical course is to try to find out if it makes any difference to human health that minute traces of various chemicals exist in human food—and if so, at what levels.
>
> This track requires low-dose, long-term toxicological testing in animals, and better ways to extrapolate these findings to the human situation. And that's a job for science. Only after than job is done can the legislators and the regulators make benefit-risk judgments that will let us get on with the business of protecting the public safety and still meet the nutritional needs of an ever greater population.

Commissioner Schmidt also added that while carcinogens pose problems it is important to remember the "equally serious questions of mutagenesis and teratogenesis."

It seems apparent that in order to shield the environment from further chemical contamination, the policy issues and the scientific issues, although interrelated, must be approached separately.[8] The role of the scientists is to describe physical phenomena—this chemical caused lesions in mouse brains under these conditions; that chemical caused cancer when fed to mice in certain quantities; those chemicals caused birth deformities when injected into chickens in designated amouts at certain ages; or to follow in detail the research track suggested by the Commissioner. Scientists can offer less definite, but still important scienific opinions on the degree to which damage to man can be predicted from damage to animals. Without knowing the levels of risk that society will tolerate, however, scientists cannot effectively differentiate between "safe" and "unsafe" substances.

Congress, on the other hand, taking into consideration the certainty or relevancy of the scientific findings, must set broad policy guidelines. Several issues suggest themselves as important for the consideration of the Nation's policymakers. Which purposes served by chemicals are worth the apparently increasing risk of their use in foods? Is it necessary to reassess—either to narrow or expand—the food and drug law prohibition on the use in food of any chemical not "required for" or

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[7] Hearings before the Subcommittee on Executive Reorganization and Government Research of the Committee on Government Operations, U.S. Senate, 92d Congress, 1st session, Apr. 6-7, 1971, p. 186.

[8] This and the following three paragraphs are adapted from James S. Turner, "The Delaney Anticancer Clause a Model Environmental Protection Law," Vanderbilt Law Review, Oct. 1971, pt. B.

"unavoidable in" food production? Which classes of chemicals should be added to the "zero tolerance" list now containing only carcinogens? Teratogens? Mutagens?

Determining the safety of a food chemical involves several steps. First, is the objective scientific determination of the discernible effects involved in the chemical's use. This determination is the responsibility of scientists.

Second, is the judgment about which of these effects is a risk and which is a benefit This judgment is ultimately made by the public, acting through its representatives and spokesman, or as individuals, but acting with a high degree of guidance from scientists, physicians, or other trained professionals.

Third, is the decision that the agreed-upon benefits of a given chemical exceed its agreed-upon risks. This is a public, not a scientific, decision, made in public forums in which scientists act as equal, though in some cases better informed, participants with other segments of society.

The Delaney clauses are a perfect model of this process at work. They delegate to scientists the responsibility for making scientific judgments and to Congress the task of making policy decisions. The scientists, after an analysis of all technical data, specify the degree of risk that would result if any amount of known carcinogens were allowed in the Nation's food supply. Congress, after considering all other relevant information, determines that the risk is unacceptable. The FDA is then charged with the responsibility of removing carcinogenic chemicals from the food supply.

In this way Congress balanced the policy function and the scientific function. In adopting the clause the Congress accepted a principle spelled out by the Surgeon General's committee more than a decade later. "Chemicals sold are to be subject to scientific scrutiny not given individual 'rights': they must be considered potentially guilty unless and until proven innocent." This is the fundamental principle of the entire food/chemical regulatory structure of the food and drug law.

In relation to cancer-causing substances, Congress heard scientists describe the known and unknown risk associated with cancer-causing chemicals. It set the policy that no chemical known to cause cancer in animals would be allowed in the food supply. The regulatory agency was assigned the scientific task of distinguishing those chemicals that cause cancer in animals from those that do not. In this way Congress set a clear public policy of caution and allowed complete scientific freedom within the realm of available information.

Anita Johnson of the Ralph Nader-supported health research group has spelled out the public policy of a consumer advocate's view of implications of the Delaney clauses in her pamphlet "Cancer Prevention and the Delaney Clause":

THE DELANEY CLAUSE IS POLICY JUDGMENT

Congress determined that since cancer scientists cannot say at what level a carcinogen is "safe" the country should not suffer any risk of cancer from chemicals deliberately added to food. The judgment has so far not been extended to pesticides, carcinogens in the workplace or water supply, drugs or other consumer products, presumably because the benefit-risk balance is more complex.

FDA has special expertise in making scientific judgments. But its personnel have no special qualifications to make social judgments on what amount of cancer risk certain food additives are worth. Under present law, FDA may determine

the side effects of a drug, such as dizziness, and then decide whether the benefits are greater than the risks. But wherever possible, FDA should be restricted to making scientific judgments, not social ones.

The recognition of Congress' role in setting social policy by adopting the Delaney clauses and restricting regulators to the making of technical or scientific judgments does not rest on the fact that the clauses deal with cancer-causing chemicals or sets a zero tolerance. These are specific facts of a specific issue not central to the responsibility of Congress to set social policy.

The President's panel on chemical and health confuses the particular aspects of the. Delaney clauses with the general requirement that Congress set social policy:

> If one is content to separate the question of technical analysis from social judgment, then one is perhaps justified in inquiring as to which part of the government has the latter responsibility, the Executive branch or the Legislative. One school of thought has urged that the Executive branch be given only the responsibility of technical analysis leaving social judgments to the Congress.[illegible] In fact, the pattern up to now has been a mixed one. In some cases, clearly the Congress has assumed the role of judge of social issues concerning how safe is safe enough. The amendment to the Food, Drug and Cosmetic Act which determines the destiny of food additives found to be carcinogenic in animals or man (Delaney amendment) is perhaps the best known example. The Clean Air Act which determines the degree of reduction of automobile emissions is another. It is interesting to note that it seems to be the very lack of sufficient information plus an implied threat in each case which has led Congress to take social judgment-making into their own hands. In most regulatory activities dealing with chemical agents, the administrator of the law enjoys some discretion either as to time of regulation or as to degree of regulation. Thus, in most cases, both the Executive and Legislative branches have opportunities for offering surrogate judgments in the public's name.

The Panel implies that there is some alternative to addressing social and technical questions separately. In fact in passing laws, Congress is almost invariably making a social judgment. Conversely, regulatory agencies—hybrid quasi-legislative, quasi-judicial, quasi-executive institutions which should not be equated with the executive branch—draw their peculiar social and legal force from the presumption that they are the repository of specialized technical knowledge which peculiarly equips them to make technical analysis or scientific judgment.

Of course, there is no hard and fast line which can be universally agreed upon as the divider between the two parts of Government and the two types of decisions they arrive at. Congress uses technical expertise to make its social judgment. The technical analysis and scientific judgment of the regulatory agencies have social impact. But there is a difference in capability between the two institutions which makes it quite important to keep the differences in their roles clearly in mind.

What is a social judgment in an atmosphere of ignorance will become a scientific, technical judgment when enough information has been gathered. It was this point which the FDA Commissioner attempted when he suggested that new scientific information needed to be developed before the Delaney clauses could be safely and effectively changed.

The kind of confusion reflected in the President's Panel report can lead to the assigning of tasks to the wrong segment of Government by transferring responsibility where ignorance rather than enlightment

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[illegible] Turner, J. S., "The Delaney Anticancer Clause: A Model Environmental Protection Law." Vanderbilt Law Review, 24; 889–902, 1971.

exists. It is of course true that both the executive and the legislative, and the regulatory agency for that matter, offer surrogate judgments in the public's name. That is the purpose of all governments. The issues of concern is on what basis do they arrive at this judgment. Legislatures operate primarily on opinion and the resolution of differences by the voting of generally equal parties. Regulatory agencies are supposed to operate through the mastery of a particular set of objective facts of which they are the recognized master. Where those facts do not exist such agencies are not properly equipped to resolve matters of opinion. It is when they attempt to resolve such matters that they tend to cause damage.

Further, it is not necessarily true that except for dramatic interventions in the process like the Delaney clauses, the administrator of the law enjoys discretion about the time or degree of regulation. The food and drug law, for example, says that only safe food chemicals are allowed in the food supply. If a chemical in the food supply is discovered to be unsafe, say it causes brain damage when eaten by men, the administrator is bound by law to remove it from the food supply. Cyclamates, according to the FDA General Counsel, was removed from the market without reliance on the Delaney clauses.

In fact, Assistant Secretary of HEW, Elliot L. Richardson, indicated to Congress in 1958 that, while the Agency would not oppose inclusion of the Delaney clauses, they were redundant. Other provisions of the law, the Department argued, were as restrictive against cancer-causing substances as the Delaney clauses.

Since there is widely acknowledged scientific ignorance about the effects of low doses of cancer-causing chemicals on humans, whether tolerance for additions of such chemicals to food should be set has been and remains a social policy question. Social policy questions are the peculiar province of Congress. Congress has adopted a social policy which bans the addition of cancer-causing chemicals to food.

This is a sound and proper procedure irrespective of whether scientists embrace it or not. In this instance that segment of the scientific community most directly concerned with research on the control and prevention of cancer strongly supports Congress' social policy choice.

III. SUPPLEMENTS TO, EXPLANATIONS AND APPLICATION OF THE DELANEY CLAUSES

Senator Gaylord Nelson of Wisconsin, one of two Senators given a 100-percent proconsumer rating by the Consumer Federation of America in March of 1974, has introduced legislation which expands the Delaney clauses' principle into the area of chemicals which cause mutagenic and teratogenic damage. If adopted by Congress, a new social policy will once again be set. Congress will have made the finding that these particular health dangers are serious enough to require special congressional attention. However, the most important part of this extension of the Delaney principle is that it does not rely on an absolute zero tolerance. The new proposed expansion reads as follows:

> *Provided further*, That no additive shall be deemed to be safe if it is found to have mutagenic or teratogenic effects when ingested by man or animal, or if it is found, after test which are appropriate for the evaluation of the effects of food additives on man or animal, to have mutagenic or teratogenic effects on man or animal except that no additive shall be deemed unsafe under this provi-

> sion if the Secretary (a) makes an affirmative finding, based on the recommendations of an advisory committee of experts (appointed by the Secretary) qualified by scientific training and experience to evaluate the mutagenic and teratogenic effects of food additives on man and animals, and includes such finding in his order issued under this subsection, that the hazard to the public health which might result by denying the use of such additive would exceed any hazard to the public health which might result by permitting the use of such additives as proposed by the petitioner, (b) gives public notice of his affirmative finding by publication in the Federal Register, and (c) within six months after the date on which such notice was so published, issues an order making his affirmative finding final.

This application of the Delaney principle suggests its flexibility. It involves a social policy judgment. Congress is asked to place certain restrictions on the use of a certain class of chemicals. But in this case, the Senator believes that scientific knowledge has developed to the point where a zero tolerance is inappropriate.

The situations presented by Senator Nelson proposing expansion of the Delaney principle suggest that debate about the Delaney clauses be drawn in several places. First, it can be drawn about the advisability of a zero tolerance for cancer-causing substances. Critics of the zero tolerance and only the zero tolerance would be happy if Congress allowed a tolerance.

Second, the issues can be drawn about the advisability of requiring that food additives be proven safe before they are added to food. Those who believe such a policy is inadvisable could only be satisfied by repeal of the entire food additives amendment.

Third, it should be argued that Congress is not competent to pass any legislation in fields which rest on scientific knowledge. If such a policy prevailed, the ability of Government to set and carry out policy would be crippled.

There are, of course, many gradations between each of these positions. Interestingly enough, as the debate about the Nelson bill begins to develop, those arguing against the anticancer clauses because they contain a zero tolerance will nearly all, if not all, be on the side of the opponents to the bill. When that occurs, consumers will be led to believe that certain opponents of the Delaney clauses really oppose all food legislation.

In fact, the Delaney clauses stand as a kind of litmus test of consumer commitment. Those who oppose the clauses are viewed by many consumer advocates, spokesman, and groups as anticonsumer. Thus, consumer groups tend to view with alarm any apparent attack on the clauses and to urge with vigor the support of the clauses. The Federation of Homemakers set the tone for many with a March 1973 resolution.

RESOLUTION OF THE FEDERATION OF HOMEMAKERS, INC., IN SUPPORT OF THE DELANEY AMENDMENT

I. FINDING OF FACT

> The basic objective of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public. As succinctly summarized by the Supreme Court of the United States:
>
> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism are largely beyond self-protection. Regard for these purposes should infuse construction of the leg-

islation if it is to be treated as a working instrument of government, and not merely as a collection of English words." (*United States* v. *Dotterweich.*)

Recognizing the impossibility of establishing safe levels for carcinogens, the Congress of the United States in 1958 incorporated the Delaney amendment into the Federal Food, Drug, and Cosmetic Act, stating:

"No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animals, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . ." (21 U.S.C. 348(c)(3)).

This amendment, which eliminated risk/benefit guidelines and prohibits the addition of any cancer-causing chemical or additive to our foods, has served as a valid safeguard against potentially carcinogenic foods being sold to unknowing consumers.

The importance of this legislation has been applauded by numerous consumer groups and supported by public governmental findings including the White House Conference on Nutrition, Food, and Health and the Mrak Commission on Pesticides and Their Relationship to Environmental Health.

Despite the recognized importance of the Delaney amendment, there is currently being observed several early signs of an intensified campaign on the part of food industry representatives, the Food and Drug Administration, and a small contingent of Congressmen to weaken or eliminate its provisions.

II. RESOLUTION

In consideration of the objective of the Federal Food, Drug, and Cosmetic Act to protect the consuming public, and in light of the noted danger of losing the strong protections afforded by the Delaney amendment, the Federation of Homemakers, Inc., by a quorum of its board of management, assembled in Arlington, Va., and voting this 19th day of March, 1973, declares its ardent support of the Delaney amendment in its present form and vigorously opposes any and all attempts to weaken or eliminate its basic protection. The uncompromising safeguard of the Delaney amendment is necessary to continue the effectiveness of the Federal Food, Drug, and Cosmetic Act as "a working instrument of government and not merely as a collection of English words."

Anita Johnson urged consumers to support the clauses which she argued was threatened by diverse industry and pseudoacademic groups. She wrote:

CONSUMERS SHOULD SUPPORT THE DELANEY CLAUSE

The Delaney Clause does not protect us from all exposure to carcinogens. Some natural foods, such as the tropical cycad nut, contain carcinogens.[87] Contact with solar radiation and products of combustion, is unavoidable. Water and air, household products and drugs, carry carcinogenic pollutants. Several thousand new chemicals are invented every year. Hundreds enter commercial channels.[88] Our environment is increasingly filled with synthetic chemicals, many not required by law to be tested for safety. Our bodies must fight a greater total carcinogenic burden.[89] Compulsory testing of all environmental chemicals is needed, as is an application of the principles of the Delaney Clauses to other chemical exposures.

Food additives are chemicals of small benefit.[90] Once added to food, additives are widely distributed, making their effects on long-range health impossible to trace, and of enormous potential danger. Exposure is easily preventable.

Prohibition of carcinogenic food additives is a sane, manageable approach to health preservation because it helps to prevent cancer. Defense of the Delaney clause from the pleas of private industry, is a top priority for all consumers.

Generally speaking, there is a growing recognization that other chemical hazards, most noticeable birth defects and genetic damage, are in need of increased attention. To supporters of the Delaney anticancer clauses, this usually means expansion of the Delaney clauses into the other areas. Thus it would appear that the defenders of the Delaney clauses would become proponents of the Nelson bill applying the principles of the clause to mutagenic and teratogenic substances.

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[87] "NAS/NRC Toxicants Occurring Naturally in Foods" (1966) 30.

[88] Council on Environmental Quality, "Toxic Substances" (1971) iv.

[89] J.A. Miller, op. cit.

[90] If a carcinogenic food additive is thought to be so crucial to civilization that it is worth possibly great cancer risk, Congress can be approached for an exemption for that individual additive.

The approach to the Delaney clauses represented by the FDA selenium petition has met with a wide divergency of consumer reaction. One school of thought argues that selenium has not in fact caused cancer in animals or men and therefore is of no concern to the working of the Delaney clauses. Another school argues that selenium is not really an essential nutrient and so should not receive the special attention that FDA has given it.

Some suggestions have made that certain mathematical models can be used to aid in handling the cancer-causing chemical problem. Generally speaking, consumer proponents of the Delaney clauses would support the use of mathematical models to the extent they would be useful in the identification of which chemicals cause concern. There is, however, great reluctance to rely on such models to establish any degree of human risk to the exposure of cancer-causing chemicals.

Dr. Marvin A. Schneiderman of the National Cancer Institute has suggested that serious thought be given to abondoning the strict risk benefit approach to safety balance and replace it with "mini-max solutions—solutions minimize the maximum possible losses." Presumably this would mean that a chemical with a slim chance of causing a massive genetic disaster in three generations would be threatened as more dangerous than a chemical with a near perfect possibility of killing one person. This would be almost a reversal of the traditional way of looking at chemical hazards. However, the general thrust of this idea has been approved by the President's Panel on Chemicals and Health. It said:

> Improved safety is possible. But to make the greatest possible health advance we ought to react most to the gravest threats, as judged by their total consequences for all our people, particularly when these threats are either well-established, or both plausibly true and long-delayed in impact. We need also to react appropriately to less certain threats that can be avoided without appreciable disadvantages. Threats of lower priority should not be neglected but need not be reacted to as strongly.

CONCLUSION

The Delaney anticancer clauses have strong scientific arguments and important cancer scientists supporting it. It is the policy decision taken by Congress in the face of ignorance about the effects of low levels of cancer-causing chemicals in food. As such it has wide support among organized consumer groups, individual consumer advocates, and even among large segments of consumering public.

There is a growing pressure for expansion of the Delaney clauses principle into the area of chemically caused birth defects and genetic damage. Consumers who support the Delaney clauses tend to support the expanding of its principles into other areas. They also tend to view any opponents to the clauses or their expansion as primarily industry based with a financial interest in reducing the regulation of chemicals in food.

In general the arguments about the Delaney clauses have been the same since their inception in 1958. The scientific information on cancer and its relation to chemicals has remained relatively undeveloped in that period. Therefore, every attempt to change the clauses in relation to food additives has been defended by the same arguments which get the measure enacted in the first place.

This flow of events has generally been regarded as a consumer victory.

[ATTACHMENT D]

THE FOOD SAFETY COUNCIL—AN INTRODUCTION

(By Dr. Richard L. Hall)

The Food Safety Council, now slightly over 2 years old, is a curious and unique organization. It responded to a need that is peculiarly characteristic of our time. And while it has antecedents, it has no precedents.

It is trite to say we live in an age of uncertainty. But while people yawn and accept the generality, they grow uncomfortable when uncertainty becomes specific—specifically when it concerns health, safety, and everyday necessities such as food.

The advance of science can narrow that uncertainty, often at great cost and effort, but it can rarely remove it. Indeed, biological science typically makes us more aware of uncertainty, or of new, different, more remote, but not necessarily less alarming uncertainties.

We are a diverse population. We have many subtle, and a few not-so-subtle biological differences. We vary in our interests, wants, and fears. The inherent uncertainties of science and our diversities of nature provide much of the basis for our current concerns over food safety. But there is an even more important social basis.

Once our food was prepared at home from locally produced ingredients. We had the confidence that comes from familiarity and a sense of control. We had never heard of carcinogens or *Clostridium botulinum*, or PBB's. We had the confidence that comes from innocence. Today most of our food is grown thousands of miles away, processed by people we never see, through equipment most of us would not recognize. We have lost the confidence that came from familiarity and control. We read almost daily of some new risk, or old risk reexamined, but which we cannot personally evaluate. We have lost the confidence that came from innocence.

Our ancestors' abilities to know, control, and evaluate their food were very imperfect, as disease records and life expectancy tables bear witness. But even those imperfect assists are depleted. We have replaced them with an elaborate, confusing array of agencies, labeling, testing, and regulation, but this has not stilled the disquiet stemming from uncertainties of science, diversities of need, and loss of confidence. This is not just, or not even a scientific problem; it is a societal one. It was to meet this need the Food Safety Council was formed.

The Food Safety Council has two principal goals. The first is to devise a scientifically valid procedure for measuring the risk of consumption of any food additive, natural ingredient or contaminant which it may be desirable to evaluate. It must be based on sound science, up to date and updatable. It must employ that elusive principle of commensurate effort. It must allocate resources among problems in proportion with the potential for solutions to those problems to promote the general health and welfare. It must intercept any unacceptable risks and it must do so with such economy of effort that it neither wastes scarce resources nor discourages useful products. That first scientific task, performed by the Scientific Committee of the Food Safety Council, is now at the state of publication for general discussion and peer review.

This leads to the second task, which relates to two key words I just used. They were "unacceptable risk," and "useful products." Animal tests and mathematical extrapolation and epidemiological studies can provide estimates of risk. They cannot judge the acceptability of that risk. Acceptance—or rejection—comes from individual or societal review of whatever advantages or benefits go with each risk and with a similar appraisal of the alternatives to that risk. It depends upon whether the risk is voluntary; that is, do we have some choice about accepting it, or is it imposed? It depends upon our own level of information or, lacking that, upon the level of our confidence in those making the choice for us. This raises the issues of consumer sovereignty expressed in choices in the marketplace and how those choices are to be made as informed as possible and as unrestricted as possible. It raises questions about those who are inherently unable to make informed choices and the extent to which provision for them must restrict everyone else. And, finally, it involves consideration of how the diversity of consumer needs can be expressed most effectively in such administrative and regulatory measures as are required.

This is an enormously complex subject in which the Social and Economic Committee of the Food Safety Council is truly breaking new ground. Their purpose is not to determine acceptable risk, but to outline the structures and procedures by which socially acceptable risk may be determined in each instance or class of instances. Their report is in preparation.

We are fortunate in having here today three members of the board of trustees. Each comes from a different and critical source of input into the council's activity. Each has contributed significantly to the progress already made. In their comments they will provide some insight into the goals of the council and how it appears those goals may be reached.

The Politics of Cancer

ELIZABETH WHELAN

It is the second leading cause of death in this country, claiming the lives of some 400,000 Americans a year: one every 90 seconds, 1,100 victims a day. One in four of us will develop it in our lifetime. An estimated 60 to 80 percent of it is caused by factors in our environment. The media inform us that our country has unusually high rates, with its incidence and mortality rates soaring, and imply that this trend results from advancing technology (industrialization) which leaves us victims of adulterated, overprocessed foods, dangerous drugs, polluted air and water, and hazardous workplaces. And now, through an elaborate network of regulations, restrictions and prohibitions, our government is supposedly going to protect us from it.

Cancer. Abnormal, undisciplined, seemingly unrestricted growth of body cells, with the resultant masses compressing, invading, and destroying contiguous tissues. Very often a painful, prolonged, undignified way to die, physically devastating for its victims, and frequently emotionally devastating for loved ones who must stand back and watch.

It should be good news to learn that our government is taking action to spare us and our children from this fate. Of course, all this effort is very expensive for U.S. consumers. But, if removing cancer-causing agents from our food and drug supply, the workplace, the water we drink and the air we breathe will markedly reduce cancer's toll, the investment of time and energy and the accompanying return to a less technological society may be worth the costs.

On the other hand, if the underlying premises that have spurred this growth in government regulation of environmental chemicals are in conflict with the scientific facts, then our government's escalating war on cancer will be an effort in futility, one with far-reaching and, I believe, deleterious effects on our standard of living. In this regard, the cornerstones of the popular wisdom about cancer and the environment are worth reexamining.

Is there a cancer epidemic?

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Apparently many people believe there is. One network television program[1] on cancer opened with the statement: "The news tonight is that the United States is number one in cancer. The National Cancer Institute estimates that if you're living in America, your chance of getting cancer is higher than anywhere else in the world." And during the Carter-Ford Presidential debates in the fall of 1976, Mr. Carter made reference to the United States as "having the highest cancer death rate in the world."

Actually, the United States ranks 21st in a list of 44 countries in cancer mortality, according to the international statistical comparisons of the World Health Organization. Scotland has the dubious honor of being "number one," followed closely by Czechoslovakia, Luxembourg, Uruguay, Austria, France, and the Netherlands. So what about this cancer "epidemic" we hear a great deal about?

Any discussion of cancer trends must distinguish between cancer incidence – the number of new cases of cancer diagnosed in a given time period for a specific population – and cancer mortality – the number of deaths from a form of malignancy in a given year for a specific population. It should come as no surprise that because of the growth of the U.S. population in the past few decades the gross number of cancer deaths has also increased. What is surprising is that despite the popular wisdom about our "epidemic," the number of new cases of cancer, taking into account all body sites for both sexes and adjustments for changes in the age distribution of the population, has *decreased* since the mid 1940s.

The incidence of certain types of cancer, specifically stomach cancers in men and women and cervical cancers, has decreased dramatically. The rates of certain other types of cancer, such as breast and intestinal cancers in white women, have stayed about the same. In men, there have been increases in the number of new cases of cancer of the prostate and the colon and increases in cancers of the esophagus and breast in nonwhite men and women. But *the only body site of dramatic increase for all Americans in the past 25 years is the lung. Were it not for the sudden and continuing up-swing in lung cancer deaths starting in 1930 the overwhelming proportion of which are the result of*

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[1] Dan Rather, "The American Way of Cancer," CBS.

cigarette smoking, the age-adjusted American cancer death rate would be declining slightly.

Causes of Cancer

In the past five years frequent references have been made to the statement that "80 to 90 percent of all cancers are environmentally induced." This figure was originally presented by the International Agency for Research in Cancer, a World Health Organization affiliate based in Lyon, France, and has, unfortunately, been subject to considerable misinterpretation. This estimate was derived by comparing the high and low cancer death rates in many countries around the world. The conclusion was that since human cancer rates differed so widely, some aspects of the environment were the bases of cancer causation. The scientists presenting the figure did not mean to suggest that we have the potential now to prevent 80 to 90 percent of human cancers, nor did they mean to suggest that environmental factors such as polluted air, water, food, and industrial chemicals played a major role. The cancer-causing factors they identified were primarily cultural in origin.

While epidemiologists differ somewhat in their estimates of the proportion of cancer deaths attributable to various causes, the majority of analyses of human disease patterns suggest that, except for superficial skin cancer, some 30 to 35 percent of cancer deaths are directly attributable to cigarette smoking (in addition to affecting the lung, tobacco exerts a carcinogenic effect on other sites, including the bladder and oral cavity); on a more speculative level another 30 to 35 percent of cancer deaths may be related to dietary habits. Perhaps, it has been suggested, diets high in calories and fat can increase one's risk of certain forms of cancer. An additional 1 to 2 percent of total cancers may be linked to excessive alcohol consumption (generally in conjunction with tobacco use) and exposure to ionizing radiation and cancer-inducing viruses.

Contrary to what emerged from a mysterious, unpublished document from the National Cancer Institute, which was widely quoted by Secretary of Health, Education and Welfare, Joseph Califano, the International Agency for Research on Cancer estimates that occupational exposure to chemicals is the underlying cause of some 1 to 5 percent of the cancer deaths that occurred in 1978. (Mr. Califano attributes 20 to 40 percent of cancers to this cause.) These deaths, however, are the result of exposure in the workplace 20 or more years ago when safety measures in chemical plants were not standard procedure as they are today, so that the 1 to 5 percent figure may overstate the problem existing today. Of all cancer risks that we as a society face at this time, the occupational risks may be no higher than 1 percent of the total and may possibly be closer to zero.

As far as we can ascertain from human epidemiological studies, food additives and pesticide residues are not responsible for any cases of cancer. Indeed, since the use of certain food additives has increased, the stomach cancer death rate has declined. While some carcinogens have been identified in the air and water of some U.S. communities, no studies have convincingly indicated either general water or air pollution as a cause of human cancer. Although there is no doubt that lung cancer death rates are higher in cities than they are in rural areas, the Royal College of Physicians concluded in 1970, after thoroughly examining the possible role of air pollution, "The study of time trends on death rate due to lung cancer in urban areas demonstrated the overwhelming effect of cigarette smoking on the distribution of disease." Other scientists, including two epidemiologists from the American Health Foundation agree: "On the basis of data accumulated in the U.S. we cannot conclude that the incidence of lung cancer is much affected by community air pollution in this country."

This should not excuse the indiscriminate or irresponsible pollution of our natural resources. There are many good and valid reasons, both health-related and aesthetic, for taking steps to keep our air and water as pure as possible. But the risk of cancer is not one of them.

The current federal preoccupation with chemicals and cancer involves many agencies. In addition to those agencies regulating materials such as cigarettes and alcohol, we are "protected" by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the United States Department of Agriculture (USDA).

The Delaney Clause

The vanguard of legislation in the chemical-cancer arena is the Delaney Clause, which now largely dictates the regulatory activities of the FDA with respect to food additives. The Clause, enacted in 1958 and authored by Representative James J. Delaney (D-NY), states: "No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals." In brief, the Delaney Clause requires the FDA to ban any food additive that is shown in any animal species, at any dose level, to cause an increased incidence of any type of tumor. Although many FDA representatives now claim that "It would have happened anyway," it is clear that the banning of cyclamates, Red Dye #2 and the recently proposed ban of saccharin are the results of the absolutism of the Delaney Clause.

The Clause has proved to be a regulator's dream. If Event A happens (cancer in an animal study) then Event B will occur (banning). This entails no weighing of cost and benefit, no scientific inquiries about what the animal study meant and how it should be interpreted – just regulatory action. Just such an inflexible and unscientific regulation led to the banning of a number of useful chemicals and most certainly has served as a disincentive for food technologists who might otherwise be seeking new types of food additives, including a variety of synthetic sweeteners. But for a while the concerned consumer, as well as those in American industry, could at least console himself that this simplistic approach was limited to the regulation of food additives.

In the last 15 years, however, a growing concern about many other chemicals and other possible environmental hazards has triggered a series of events which may ultimately lead to a Delaney-like regulatory approach to all the synthetic – and perhaps some natural – chemicals in our lives.

The National Cancer Institute, Environmental Protection Agency and Occupational Safety and Health Administration began, in the 1970s, to examine possible environmental threats and wrestled with alternatives for identifying and regulating carcinogens. Industry established the Chemical Industry Institute of Toxicology with the announced objective of creating the best toxicology testing operation in the world. During 1975 the NCI attempted to develop general criteria for assessing whether specific environmental agents constituted a carcinogenic hazard in humans. But in issuing a report in June 1976, the NCI concluded that no simple guidelines could be set, since evaluating chemicals is a complex process characterized by many imponderables and often requires expert scientific judgment in each case.

But the EPA took a different course. In an effort to develop a policy for evaluating pesticides, an effort that overlooked the NCI panel's conclusion that broad guidelines in judging carcinogens were not practical, the EPA issued what it termed "Nine Principles of Carcinogenicity." In summary, these principles stated that any chemical that induces either *benign or malignant* tumors in animals must be considered to be a carcinogen capable of affecting man and that such a chemical must be assumed to pose a hazard even at extremely low levels of exposure. EPA applied these principles (which, because they are not fundamental truths, laws or doctrines, might better be called "propositions") to the pesticides, aldrin and dieldrin, which at high levels cause liver tumors in mice. The agency termed these substances "imminent hazards" and banned them, despite the fact that these agricultural chemicals did not cause tumors in other animals and had no carcinogenic effect on workers who for many years had been exposed to the chemicals at levels many hundreds of times that of the general population.

At the same time, OSHA was considering how to carry out its legal mandate, the protection of workers in the workplace, particularly in terms of possible exposure to occupational carcinogens. During its first years OSHA (which was created in 1970) was primarily concerned with such mishaps as falling off ladders and crushing fingers in machinery. The carcinogen matter was a relatively new one for them. Indeed, the agency was under increasing criticism, some internal and blatantly self-serving, for having regulated only a handful of chemicals as carcinogens. In an effort to increase its ability to move more quickly against possible cancer-causing chemicals in the workplace, OSHA, in late 1977, issued a proposal abandoning its previous substance-by-substance approach to the regulation of carcinogens and establishing a standard fill-in-the-blank type schema. Specifically, OSHA now proposes that a chemical be identified as a "confirmed carcinogen" if it increases the incidence of tumors or decreases latency periods between exposure and onset of tumors – malignant or benign – in either humans or two mammalian species, or one animal species if the test is replicated or considered by OSHA scientists to be convincing.

While at first glance, the OSHA regulation may appear to have more flexibility than the Delaney Clause, it, too, places the label "carcinogen" on any chemical that increases the incidence of any type of tumor, in any animal, in any dose, possibly by any route of administration (including skin application or injection). In the sense that it assumes that *any* type of tumor, malignant or benign, is cancer, it is even more inflexible than the Delaney Clause.

While these OSHA regulations would apply only to the workplace, they could, in effect, set a national standard for the definition and regulation of carcinogens. If they are approved as scientifically valid, they could very well become part of the regulatory apparatus of all health-related agencies, thus being applied to chemicals in the air, water, cosmetics, drugs, and food.

A National Cancer Policy

As the various regulatory agencies were pondering their own individual cancer policies, four of these regulatory agencies charged with protecting workers and consumers from carcinogenic substances began to develop what they hoped would be a national cancer policy. The EPA, CPSC, FDA and OSHA developed their proposal under the Interagency Regulatory Liaison Group (IRLG), which was set up by President Carter to coordinate regulatory activity. The report of this interagency group resembles OSHA's proposal in that it relies heavily on animal tests and accepts as a major premise that cancer studies involving mice, rats or other mammals are valid methods for judging a compound's potential effects upon people and that there is currently no reliable way to predict a threshold below which human population exposure to a carcinogen has no effect on cancer risk. But the IRLG document did show some insights that the policies of the individual agencies did not. Specifically, the IRLG paper stresses risk assessment, estimating the degree of risk involved in exposure to a given chemical rather than labeling all potentially harmful substances as "carcinogens." This is significantly different from grouping all potentially carcinogenic substances as carcinogens and regulating them all in the same manner. There is approximately a million-fold difference between the cancer-causing activity of aflatoxin (a proven animal carcinogen in a number of species) on one hand and the disputed carcinogenic potential of saccharin on the other.

It is very difficult to criticize any program aimed at cancer prevention. We all agree that reasonable and effective methods should be employed to reduce the public's risk of suffering from this dreaded disease. But the Delaney Clause, the EPA "Principles," the OSHA regulations and even the new interagency proposal seem to be so intent on preventing cancer *at any cost* that they have overlooked some obvious and sometimes disturbing scientific realities.

First, all three regulatory approaches make the assumption that most cancers are caused by potentially avoidable exposures to chemical carcinogens. The Delaney Clause assumes these chemicals are likely to be food additives. The EPA Principles assume that they take the form of carcinogenic pesticides. The OSHA regulations assume that the offending chemicals are in the workplace, injuring workers and then possibly escaping to pollute our air and water supply.

But as has already been pointed out, the pieces of the cancer puzzle which have been assembled to date do not support these assumptions.

Indeed, an examination of the causes of human malignancies suggests that the combined FDA, EPA and OSHA efforts to remove cancer-causing agents from our food, water, air and workplace would only have the potential for reducing our cancer mortality by between 0 and 5 percent.

Second, all three regulations are, to varying degrees, based on a double standard, one that demands action against a man-made chemical, while no action is required to eliminate similar hazards caused by naturally-occurring substances. The Delaney Clause is specific in this regard; its legislative impact is limited to chemicals *added* to food. The EPA principles and OSHA guidelines are ambiguous but appear to be only concerned with "artificial" agricultural and occupational chemicals. As a result, a useful artificial sweetener like saccharin may be banned on the grounds that it induces tumors in Canadian rats while there is strong scientific evidence that egg yolk, egg white, selenium, caffeine, lactose, maltose and vitamin A – which will not be banned – are carcinogenic in at least one species of mammalian test animals.

Third, all three individual regulations are inflexible, requiring regulatory action on the basis of animal experimentations, assuming that laboratory animals are excellent predictors of the cancer-causing potential of a chemical in man. Indeed, proponents of all these regulations contend that all chemicals that cause cancer in man cause cancer in animals; the inference being, then, that mice are little men.

While it is true that most – but not all – known human carcinogens are cancer-causing agents in laboratory animals, *the opposite is not true* – not all animal carcinogens are known human carcinogens. Drugs such as sodium penicillin and phenobarbitol, known animal carcinogens, have no known cancer-causing effect on humans. If the philosophy of the Delaney-OSHA-EPA regulations were applied to the oral contraceptive – which contains synthetic estrogen – the Pill would never have been approved, because all estrogens, natural or otherwise, have carcinogenic properties.

The fact that the OSHA regulations, unlike the Delaney Clause, assume that the appearance of benign as well as malignant animal tumors indicates a carcinogenic potential for man is even less scientifically tolerable. While most authorities believe that the appearance of benign tumors should be a warning, there is no reason to immediately classify them as "cancerous."

There is no doubt that animal experimentation plays a critical role in evaluating chemical safety. Some of the most important medical discoveries had their beginnings in animal experimentation. We are not suggesting that we should rely solely on evidence of human experience in judging a substance's safety. Epidemiology does have its limitations, primarily that it takes five, ten, twenty or more years for some human carcinogens to reveal their deadly characteristics. But we simply cannot be guided by laws that assume that the laboratory animal is an infallible predictor for man. Animal experiments need to be interpreted and put in proper perspective.

Possible individual species or strain susceptibility must be taken into account – as well as other unique circumstances that may be responsible for whatever positive results appear. It is known, for instance, that animals differ from humans in their reactions to various chemicals. Morphine has a directly opposite effect on the cat than it does on human beings. It is a very useful analgesic drug for man, but when it is given to a cat, the animal becomes restless and belligerent.

Ensuring a Sound Basis for Prohibition

If a food additive or other industrial or environmental chemical, when ingested by a group of rats, leads to an increased incidence of malignant tumors of the bladder, liver, or other organ, the results are worth noting. But that observation is not in itself a sound basis for condemnation or prohibition. Instead, such an observation should stimulate similar tests on other animals. When the results of a series of different tests on different animals are in, the scientific decision-making process should begin. Were the results consistent? Did the chemical have a carcinogenic effect in more than one species? Certainly, one study detecting cancer in animals should not negate a dozen others reporting no cancer. What about a dose-response relationship? Did the incidence of tumors increase as the dosage of the chemical was increased? Does the chemical being evaluated have any characteristic that might lead one to suspect it is carcinogenic? Are there specific factors that promote or inhibit the carcinogenic effect of this substance in a laboratory animal? Is there any human epidemiological evidence available on the substance which would support or fail to support the laboratory findings? Years of safe use by humans should generally carry more weight than one limited animal evaluation. Does the chemical perform an important function? Are there alternatives? What would be the cost of banning or severely regulating it? The answers to some, if not all, of these questions may provide a basis for sound, scientific decision-making. There can be no set criteria for judging carcinogenic activity, but there can be a consistent and scientific method of analysis. The data provided by laboratory experimentation should provide but one input into a complex evaluation procedure.

Fourth, the OSHA regulations, like the Delaney Clause and EPA Principles before them, are unrealistic and, indeed, anachronistic in that they assume that if a large amount of a substance induces cancer in animals or humans, even trace amounts – truly minute quantities – could be carcinogenic, too, and thus should be eliminated from the environment. With our sophisticated means of detecting minute levels of a substance, the zero tolerance principle is particularly inappropriate. The process of producing cancer in the most sensitive species at any dose level by whatever route and then assuming that trace amounts of that chemical might cause cancer in man, perhaps despite human evidence to the contrary, is nothing short of ridiculous.

By assuming that any chemical at any dose that induces any type of tumor in any animal is a potential cancer threat for humans and by setting standards which will ban that chemical or require expensive, superfluous restrictions, our government carcinogen policy will, in effect, be saying, "If there is even the slightest possibility, no matter how hypothetical and no matter what the cost of regulating procedures may be, take action."

Stopping the technology at even the hint of a problem is going to be very costly indeed.

As is always the case, the major costs of regulation are hidden ones, manifesting themselves in higher taxes, higher prices in the marketplace, reduced availability of supplies and services, and, in this case, increased dependence on other countries to supply us with goods that we can no longer make. Very often these costs simply show up in nickel and dime price hikes on common products and become indistinguishable in the overall spiral of inflation. What is clear, however, it that the regulatory steps now being proposed by OSHA are going to be even more expensive and are going to affect every one of us.

If applied literally to all chemicals in our environment, the OSHA standards might demand rigid protective gear for those who make their living frying eggs (as mentioned earlier, both whites and yolks are animal carcinogens) and could lead to the disappearance of major industries and materials we now take for granted, for example, the dry cleaning industry (with its dependence on perchloroethylene), cosmetics (one hair-coloring ingredient, 2,4-DAA, has been found to cause tumors in rodents, which would make it an unacceptable material for the workplace), foods (continued testing of additives and pesticides will inevitably lead to more and more isolated studies noting animal cancers), everyday products (perhaps among them insulation materials, because they have traces of asbestos, plastic bottles because of a speck of vinyl chloride monomer, and gasoline because it has more than a trace of benzene).

But it is very likely that the cancer standards *won't* be applied literally because that would only make the government look more foolish than it already does and lead to more jokes, like the one about a substance called W-A-T-E-R being banned because an FDA researcher put his head in it for 20 minutes and died. It is unlikely that the regulations will be applied to the point that we shall destroy ourselves in the process. Instead of arousing the ire of Mr. and Ms. America, or risking losing the support of labor union leaders who begin to question whether they want to pay for this higher degree of safety by having fewer jobs available, the regulatory efforts will likely be focused, as they have been in the past, on areas where the impact will be more subtle, more indirect, although certainly not less costly.

The Cancer War: An Expensive Failure

It seems clear that the federal attempt to protect us from cancer, as reflected in the Delaney-EPA-OSHA-type regulations, is going to be a very expensive failure. These regulations focus a great deal of time, attention, and resources on environmental factors that contribute little to the nation's cancer burden. Obviously, we need to test our food additives to make sure that we are keeping hazardous materials out of our food supply. Highly toxic and/or carcinogenic materials should be also carefully supervised in the workplace. We realize that industry does *not* always voluntarily monitor itself. Some of the smaller chemical industries have been callously irresponsible about human exposure to known cancer-causing agents.

But an enormous, highly restrictive, inflexible, and expensive government regulatory system is not necessary. Because we have experienced tragedy in the past as a result of conditions that were extreme in their promiscuous exposure to carcinogens, we do not now need to go to the other extreme, purchasing a far higher degree of safety than is necessary and instituting measures that will raise our taxes and the prices of goods and services without saving even one additional life. There are means by which we can accomplish the same goal: reducing the very small number of known chemical cancer hazards that may still exist in our environment by means of a less generalized, more focused approach, one that acknowledges degrees of risk and seeks on a case-by-case basis the counsel of the country's leading scientists, lawmakers, industry leaders, and consumer representatives.

Instead of seeking a risk-free environment, we should be moving toward the identification of acceptable levels of risk. In doing so, we would *not* be saying, "If you want this product, X number of workers will develop cancer" (which, indeed, is exactly the type of trade-off we willingly make using automobiles, airplanes and swimming pools). It is possible for us to set levels of chemical exposure which according to all scientific evidence do not significantly raise anyone's disease potentiality.

While concerns and government regulatory efforts are now focused on the possible link between technological development, environmental chemicals, and cancer, it is clear that the United States does not have a unique cancer pattern and that, with the exception of lung cancer, there is no cancer epidemic. Air and water pollution, modern food technology, and "industry" are not at the root of our cancer problem. The parts of the cancer causation puzzle now assembled point directly to harmful aspects of our individual habits, particularly cigarette smoking and dietary excesses.

Yet, popular wisdom prevails and new laws, regulations, and bannings are being proposed. And popular wisdom will continue to prevail unless there is an increased public awareness about the disastrous impact regulatory decisions based on misinformation can have.

In recent years, the few scientists who have stepped forward to report the facts about chemicals, cancer, the environment, and health have been met with skepticism and antagonism. Critics often label them apologists for the food or chemical industries, paid for issuing these unorthodox views. As a result, an unrealistic dichotomy has resulted between the self-appointed "consumer" groups who condemn the cancer-causing impact of industry and its chemicals and the much-maligned group collectively known as "industry," which understandably is speaking (or not speaking) in its own defense.

In reality, however, neither of these groups represents the basic interests of the American consumer on questions relating to cancer and the environment.

Traditional consumerists, who have successfully called for bans on DDT, cyclamates, TRIS, Red Dye #2, and other chemicals and who are now turning their guns to saccharin, nitrite, hairdyes, and hamburgers, appear to be demanding safety at any price, no matter what a ban on a chemical might do to availability and price tags and no matter how small or hypothetical the benefits of such a ban might be. "Industry," on the other hand, is comprised of business people who are quite legitimately seeking profits. The costs of regulations are simply passed on to the consumer, and industry always can come up with new products to sell. To go to an improbable extreme, if the chemical industry were put out of business, firms could always regroup to sell organic food, water purifiers, or air masks for city dwellers. In the long run, it is the *consumer* who has the most to lose in the chemicalphobia debate.

If modern-day chemicals cause cancer (and by chemicals we mean our pharmaceuticals, processed foods, and the other products of technology that make our life easier) then that would be another question. But in most cases no such cause-and-effect relationship exists, and we may soon find ourselves without some very basic, useful items, while we spend more of each dollar in taxes to pay the regulators – all this without preventing even one case of human cancer. This is an enormous price tag for nothing.

Cancer is a major public health problem in the United States, the second leading cause of death. It is a problem that demands research attention. But our "war" on cancer will be lost before it begins if we continue to misidentify the enemy.

We would be wise to look before we take a large leap backwards, assessing what costs are involved in such a move. For example, in addition to dealing with the economic burden of government regulation, by accepting a sweeping, uniform carcinogen policy, we will be paying yet another indirect and very significant cost. By investing such a large portion of our tax dollars in programs that appear to have no payoff in terms of cancer prevention, we will be detracting attention from the real war on cancer, one that might provide us, for example, with the formula for a safer cigarette, a better understanding of how diet and disease may be linked, and more complete information on the viral causes of some cancers. In this sense, government regulation may prove to be cancer's ally, leading us to wonder if our regulatory bodies themselves might be well-advised to post a label, "Warning: This agency may be harmful to your economic and physical health."

Steven Fustero—*Environment*

Unnecessary

BY ANITA JOHNSON

Do We Need to Poison Ourselves?

EXPOSURE TO TOXIC CHEMICALS is endurable when important benefits are provided. But many hazardous chemicals provide consumers with trivial benefits or no benefits at all. Moreover, countless consumer products are put on the market in spite of ignorance of their benefits and of their true effects.

Drugs

Consumers of over-the-counter drugs, for instance, are likely to be exposed to witches' brews of untested ingredients, many unnecessary for any medicinal purpose. The best-selling cold medicines contain a variety of unproven ingredients. The value of two of the three medicinal ingredients in Contac, advertised at a cost of at least $10 million a year, are unproven by the manufacturer. Three out of four of Coricidin Cough Medicine's major ingredients are unproven, according to the Food and Drug Administration (FDA). Dristan, with $20 million in annual advertising, has two unproven ingredients out of four. Vicks Cough Syrup has five out of six.[1] In addition to these ingredients, cough and cold medicines have a plethora of dyes, perfumes, flavors and sweeteners, texturizers, vehicles and preservatives which the manufacturers add for cosmetic reasons (and which are not on the label).

The case of chloroform illustrates the folly of using these untested unnecessaries in drugs. Until 1976 chloroform was widely added to cough medicines, toothpastes, and mouthwashes to provide a tingly flavor. There had been suggestions for thirty years that chloroform caused cancer, but the manufacturers were not particularly curious about this possibility.[2] In 1972 the National Cancer Institute—at the taxpayers' expense—initiated animal studies, which showed that the substance caused cancer in mice and rats.[3] Like the coal-tar dyes, chloroform is a member of a bad family,

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Chemicals

the chlorinated hydrocarbons, many of whose members have caused cancer in animal studies and in humans. Members of this one family include vinyl chloride, bis chloromethyl ether, trichloroethylene (a solvent found, until recently, in decaffeinated coffee), and DDT. Products which formerly contained chloroform included Parke-Davis's Benylin, Upjohn's Ceracol, Wyeth's Phenergan, and other cough medicines such as Pertussin and Coricidin.

Consumers are also bombarded with unnecessary toxics prescribed by their doctors. For example, doctors frequently prescribe antibiotics for the common cold, a use which is irrational because antibiotics are effective against bacteria, not viruses.[4] Antibiotics such as clindamycin may produce such serious side effects as life-threatening colitis and should be prescribed only for very special types of infections (potentially life-threatening anaerobic infections).[5] Ampicillin is frequently prescribed for acute tonsillitis and strep throat although it produces far more serious side effects than the preferable, and cheaper, penicillin.[6]

Sex hormones are prescribed for women in grossly inappropriate circumstances, entailing serious risks. Progestins such as, for example, Provera and Delalutin were widely prescribed for pregnancy-related conditions over 400,000 times in 1976, the year *after* warnings were issued that these substances are dangerous in pregnancy because they cause birth defects.[7] More than three-quarters of the 7.7 million annual prescriptions for Premarin, an estrogen for the symptoms of menopause, are inappropriately prescribed, considering the fact that this substance causes cancer of the uterus, with the definite possibility that it causes breast cancer as well.[8]

Saccharin

Saccharin is a good example of unnecessary chemical exposure. Although it has been on the market for decades, no benefit other than mere taste has ever been demonstrated. From the available evidence there is no indication that saccharin aids in dieting. Animal studies have shown that those animals fed artificially-sweetened drinks make up for the fewer calories in the drink by eating more solid food.[9] Other animal studies have shown that saccharin lowers blood sugar, which is significant because lowered blood sugar is one trigger for appetite.[10] This lowered blood sugar has also been caused in saccharin studies in humans, at doses equal to one-third of a can of diet soda.[11] Thus, not only has a diet effect not been shown for saccharin but the available evidence indicates that saccharin makes it harder to diet. A National Institute of Medicine study of saccharin in 1974 concluded: "The data on the efficacy of saccharin or its salts for the treatment of patients with obesity, dental caries, coronary artery disease, or even diabetes has not so far produced a clear picture of the usefulness of the drug."[12]

The fact that a number of prominent diabetes experts believe that saccharin "has no special place in the diabetic's regime" indicates that saccharin for diabetes, too, is more a custom than a necessity. The American Dietetics Association has taken the common-sense view that low-calorie food can be made appealing without artificial sweeteners by using natural condiments such as ginger and grated coconut.[13]

The FDA determined last March that saccharin is a carcinogen. The determination was made when the results of a Canadian rat study became known. That study was the last of at least eleven studies in which saccharin produced cancer—in one study at doses as low as the equivalent of 1.6 bottles of diet soda per day.[14] These studies have been followed by several human studies, with the same results.[15] The ban triggered a widespread outcry, and Congress delayed its implementation for 18 months. The outcry was the result of a public as yet unable to scrutinize critically the common products around it, to separate out the promotional claims from the real benefits, and as yet unaware of the value of animal tests in preventing human injury.

Food Additives

The coal-tar food dyes are also a cause for serious concern. The majority of these dyes are on a so-called "provisional

The FDA is required by law to prevent the addition to food of any amount at all of any cancer-causing chemical. (All lab photos courtesy of FDA)

list," which means that they are acknowledged by FDA to be of unknown safety. Six coal-tar dyes have been permanently approved by FDA as proven safe. In fact, none of these dyes has been adequately tested. That each presents a definite health hazard is suggested by animal studies. Citrus Red 2, used to glamorize Florida orange skins, was determined by the World Health Organization in 1969 to be a carcinogen.[16] Blue No. 1 (Brilliant Blue), used in beverages, candy, and baked goods, is banned in Britain as a carcinogen.[17] Orange B, used to color hot dogs and sausage skins, is a suspect carcinogen, as is Red No. 3, used in candy, puddings, frosting, and cookies.[18] Yellow 5, the most extensively used food color, found widely in virtually every category of processed foods, creates serious allergic reactions in a small proportion of consumers exposed to it. The long-term animal studies on this dye provide little information one way or the other on carcinogenicity.[19]

Public exposure to coal-tar food dyes can be enormous. Based on FDA calculations, a twelve-year-old child may already have eaten as much as three pounds of coal-tar dyes, while ten percent of children will have eaten over one pound by that age.[20] Why should the risk of cancer or any other health risk be endured for the sake of hair coloring or food coloring? A Gallup Poll commissioned by *Redbook* magazine, conducted in March 1976, found that 59 percent of women surveyed said they favored banning food additives used only to improve the appearance of food, even if there was no positive evidence of harm.[21]

Food additives have been a special object of scrutiny since 1958 when the law first required many food additives to undergo safety testing prior to marketing. The food additives law contains the only specific anti-cancer clause in Federal law, the Delaney Clause, which forbids addition to food of any additive which causes cancer when fed to animals.[22] The FDA is prohibited from permitting *any amount* of a cancer-causing chemical to be added to food, large or small, cup-full or thimble-full. The reason for this stringent law is that cancer-causing chemicals, unlike other toxic chemicals, may be dangerous to some people in very small amounts. Carcinogens seem to be able to penetrate into the DNA of a cell in minute doses and inflict a wound which causes the cell reproduction process to go haywire.[23] In addition, tiny amounts of carcinogens seem to act cumulatively with other carcinogens in the environment, such as water or air pollutants, to become more dangerous, and they seem to be activated by other chemicals which are harmless in themselves, such as croton oil, a chemical commonly found in European cosmetics.[24] Other kinds of chemicals appear to have a level which is safe for everyone and a level which is hazardous for everyone, but individuals vary greatly (and unpredictably) in their vulnerability to carcinogens. One person smokes three packs of cigarettes a day and gets no cancer while another gets cancer from two cigarettes a day. Once a chemical is determined to cause cancer in reliable, well-designed animal studies, there is no determinable safe dose.[25]

Industry frequently ridicules the value of animal studies on the basis of the large doses used and is currently working to repeal the Delaney Clause. Large doses are essential for animal studies. They compensate for the short lifespan of animals relative to humans and for the fast metabolization and excretion of chemicals by animals compared to humans. High doses are also essential to increase the *rate* of cancer caused so that it will show in the small number of animals, usually 50, used in the tests. Low-dose animal studies would not be valuable in detecting cancer-causing chemicals, as industry well knows when it advocates using low doses only. High-dose animal studies are considered by cancer experts to be highly predictive of human harm.

Cosmetics

Like other cosmetics, hair dyes have long been marketed with little concern for health. Early last fall, publicly funded animal feeding studies revealed that a component of the majority of permanent hair dyes—2,4-diaminoanisole—causes cancer. Called 2,4 DAA, this ingredient is found in Clairol, Revlon

To a certain extent, proper labeling will help consumers to protect themselves and will encourage manufacturers to shift to less complicated products. But labeling of known toxicants is no solution if there is a serious hazard involved without any compensating serious benefit.

and L'Oreal products, among others. This finding would not be particularly alarming for a hair dye except for the fact that FDA studies had previously indicated that 2,4 DAA applied to hair is absorbed through the skin. Once through the skin into the bloodstream, the chemical will entail all the risks it would if eaten. The fact that 2,4 DAA is a carcinogen should come as no surprise, since it is a chemical cousin of benzidine and other dyes known since the early 1950s to cause cancer in textile workers. On January 6 of this year, the FDA announced plans to require warning labels on these products.[26] On January 13 the National Institute for Occupational Safety and Health announced that 2,4 DAA should be considered a human carcinogen since cosmetologists have significantly higher cancer rates than other occupations.[27] Another common hair dye, lead acetate, found in Grecian Formula and other products, also causes cancer in animals and appears to cross the skin into the bloodstream.[28] The National Cancer Institute (NCI) is nearing completion of animal studies on several other suspect coal-tar hair dye ingredients long marketed without scrutiny by the manufacturers.

Hexachlorophene is a chemical which virtually pervaded the cosmetic supply until 1973. Hexachlorophene inhibits the growth of certain kinds of bacteria and, on that basis, was added to practically everything from lotions to aerosol sprays to soaps on the theory that anything that kills bacteria must be beneficial everywhere. In fact, it is highly questionable whether routinely killing certain skin bacteria is beneficial. Apart from this, hexachlorophene was, after many years of use, shown to cause central nervous system damage in animal studies. In addition, hexachlorophene in talcum powder was responsible for the death of about fifty infants in a French nursery, while a West Coast study showed that premature infants bathed in hexachlorophene had numerous spine and brain lesions.[29] Hexachlorophene is yet another chemical which was untested for many years, which is clearly toxic to humans, and which was totally unnecessary from the very start.

Flame Retardants

Last April, the Consumer Product Safety Commission banned the use of Tris, a flame-retardant, in children's sleepwear.[30] More recently, the public has been warned about the potential hazards of the flame-retardant Fyrol FR-2, which has been used as a Tris substitute.[31] Scientific studies on Tris have indicated that Tris can cause cancer, genetic damage, and sterility in test animals.[32] It is present in fabric at levels up to five percent by weight of the entire garment. Flame-retardants have been added to children's sleepwear to achieve the flammability standards set by the CPSC. While some sleepwear fabrics are naturally flame-retardant and do not have chemical flame-retardants added, and many consumers would prefer to buy these, there are no instructions on the label to alert consumers about the presence or absence of this class of chemicals.

Labeling

Hazardous chemicals entering the marketplace untested, only later to be detected, are a fact of life and will continue to be so until our regulatory laws are strictly enforced by government agencies. To a certain extent, proper labeling will help consumers to protect themselves and will encourage manufacturers to shift to less complicated products.

The value of ingredient labeling, of course, presupposes that consumers know what ingredients to avoid and that adequate information on the ingredients has been generated by the manufacturers or others. Nevertheless, even this bare minumum is not always the case with consumer products. Many foods are not required by law to list food additives. Included among these are alcoholic beverages which frequently contain a large number of unlabeled chemicals.[33] Flame retardants are not labeled, nor are the many extraneous ingredients in drugs, such as flavors and dyes.

Patient information on prescription drugs is desperately needed. At the present time, the law requires detailed product information on prescription drugs, but this information is distributed

Food additives have been a special object of government scrutiny since 1958 when the law first required safety testing prior to marketing.

for the benefit of the doctor, not the patient. If patients received information on the purposes for which the drug was prescribed, warnings, side effects, etc., much inappropriate drug use by doctors could be curbed by consumer vigilance. If consumers could see the warnings on the frequently-ignored physician labeling of the antibiotics clindamycin and lincomycin, warnings that these drugs can cause life-threatening colitis, it is unlikely that they would take them for acne or colds. Pregnant patients would be unlikely to take sex hormone prescriptions knowing of the possibility of endangering the fetus. Two bills have been introduced in the Congress to require so-called patient package inserts for prescription drugs HR 9541 and S-2040. The Pharmaceutical Manufacturers Association and the American Medical Association believe that, if such inserts are used, they should contain information on how to carry out a doctor's orders but should exclude information which would help the patient evaluate the doctor's prescription, such as what conditions the drug is approved to treat.[34] Obviously, patient drug information will help stop overmedication only if it is complete. Also, this information is needed at the doctor's office, where the decision to prescribe a drug is made and informed consent given by the patient, not solely at the pharmacy once the drug is prescribed and paid for.

The Occupational Safety and Health Administration is currently drafting regulations to require full labeling which would include the names and toxic effects of chemicals found at each workplace, and, in some cases, it would require the availability of detailed information sheets on the hazards for the workers involved. Such a requirement would be an important step for worker health, since workers are frequently unfamiliar with chemical hazards until it is too late. In some cases, employers have even removed

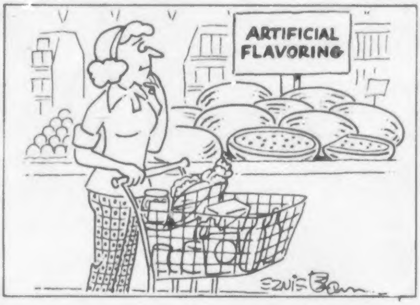
Animal testing is the principal means used by the FDA to determine whether a substance is cancer-causing. Industry representatives frequently argue that the results of such tests are not valid for human populations.

manufacturing labels from cans of chemicals entering the plant so that workers cannot learn the identity of what they handle. Full disclosure of hazards will help individual workers to make more informed judgments about their jobs and their work practices and will undoubtedly increase labor union interest in occupational health.

Labeling of known toxicants is, of course, not the solution for the many chemicals which involve serious hazard without serious benefit such as food additives. Labeling of saccharin is not a viable alternative to a ban for this reason. Moreover, it is not realistic to believe that adult consumers seriously weigh the benefits of each bottle of Tab against the risk of getting cancer at age 55. Children definitely do not, nor do the unborn, known to be at special risk, nor do the adults who get saccharin in restaurants and other places unbeknownst to them.

Labeling is only of limited help when the ingredients of consumer products have not been tested—as in the case of the cough and cold remedy ingredients or of the coal-tar dyes. A wide variety of food additives which have not undergone thorough study are on labels because the FDA has allowed them to escape through the testing loophole in the law called "generally recognized as safe" additives,[35] or has approved them on the basis of inadequate data.

Until the performance of government agencies reaches that point where we can be sure that a chemical in a consumer product has been thoroughly tested and proven safe, the public's best recourse is to demand full labeling of ingredients and then to stay away from all products with ingredients which are not absolutely necessary. The appropriate presumption is that, until something is proven safe, we should not be exposed to it. Obviously, this is a reversal of the presumption of the last decades that the marvelous new products brought to us by the chemical industry are wholesome and valuable.



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28. See International Agency for Research on Cancer [IARC] Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man (1972) Lyon, France 1:47; National Cancer Institute Bioassay Experimental Design Status Report, Contract No. 712166, Nov. 8, 1977, pp. 11-12; Marzulli et al., Exploratory Skin Penetration Findings Relating to the Use of Lead Acetate Hair Dyes, in Proceedings of the 22nd OHOLO Conference, forthcoming, p. 11, and other references in "Comments of the Environmental Defense Fund on the FDA's Proposal to Postpone the Closing Date for Lead Acetate" (42 Federal Register, Dec. 13, 1977, 62490).

29. The Medical Letter 18, 1 (1976) and citations therein.

30. 42 Federal Register 105 (1977): 28060.

31. New York Times, October 15, 1977, p. 24.

32. National Cancer Institute, Bioassay of Tris (2,3-Dibromoprophyl) phosphate for Possible Carcinogenicity, March 16, 1977; Blum, et al., Science 195, 17 (1977).

33. Congressional Record, March 12, 1973, E1471.

34. See testimony of PMA and AMA in Hearings before the House of Representatives Health Subcommittee, Drug Safety Amendments of 1976 (June 1976), pp. 115, 128, 175.

35. 21 U.S.C. 348, 321(s).

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

FEDERAL EFFORTS TO PROTECT THE PUBLIC FROM CANCER-CAUSING CHEMICALS ARE NOT VERY EFFECTIVE

DIGEST

Although up to 90 percent of human cancer, according to some scientists, is environmentally caused and controllable, Federal efforts to protect the public from cancer-causing chemicals have not been very effective.

Many chemicals cause cancer in animals, but Federal agencies have trouble determining which also pose a cancer threat for humans because

--there are no generally accepted principles concerning environmental causes of cancer (see p. 17),

--there are no uniform minimum guidelines for testing (see p. 17),

--test data are not always complete or appropriate (see p. 19), and

--scientists cannot accurately predict human response to chemicals on the basis of animal test results (see p. 20).

The Director of the National Cancer Institute is responsible for directing Federal efforts and should, with the cooperation of other involved Federal agencies, develop a uniform Federal policy for identifying and regulating cancer-causing chemicals.

The policy should at least cover

--the information needed to regulate cancer-causing chemicals,

--which chemicals should be tested in animals,

--how tests should be conducted,

--how results should be evaluated,

Reproduced from U.S. General Accounting Office. Federal Efforts to Protect the Public from Cancer-Causing Chemicals Are Not Very Effective; Report to the Congress by the Comptroller General of the United States. (Washington) 1976 (MWD-76-59, June 16, 1976) 57 p.

--how human risk can be assessed from animal studies, and

--what factors other than public health should agencies consider. (See p. 38.)

Although the Department of Health, Education, and Welfare agrees that a Federal policy is needed, it does not agree that a formal effort, headed by the Director of the Institute, is necessary. GAO believes a Federal policy can only be developed with the active support of every involved Federal agency, and the Institute Director, as head of the National Cancer Program, should coordinate these efforts. (See p. 35.)

GAO is also recommending that the Food and Drug Administration have all approved and proposed food additives tested for their cancer-causing potential because it had not been requiring data from such tests when the additives were unintentionally added to the food in amounts less than 1 or 2 parts per million. The Department disagrees, saying the risk of cancer is remote and the costs for testing would be substantial. (See pp. 12 and 37.)

EXTEND FEDERAL AUTHORITY TO CIGARETTES

Tobacco and tobacco products are on the Institute's list of known human carcinogens; since 1964 the Surgeon General has reported to the Congress on the relationship between smoking and cancer.

For the past 2 years the Secretary of Health, Education, and Welfare has recommended that the Congress give the executive branch the authority to control hazardous ingredients--such as tar and nicotine--in cigarettes.

GAO is suggesting that the Congress

--request the Department to prepare a study showing the available options for regulating tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate and then

--consider giving the Department or some other appropriate agency the specific authority to regulate tobacco and tobacco products. (See p. 36.)

BURDEN OF PROOF

The Government can control cancer-causing chemicals, but an important factor in achieving public protection is whether action is taken before or after the chemical gets into commercial use and the environment.

The Government requires only the manufacturers of pesticides, drugs, and food and color additives to prove their products' safety before marketing them. The Government must prove the health hazards of other products, air and water pollutants, and occupational hazards before initiating action.

The proposed toxic substances legislation would make manufacturers prove a chemical's safety before it is marketed rather than having the Government prove that it poses a hazard after it is marketed. GAO believes this legislation would improve Federal efforts to protect the public from cancer-causing chemicals. (See p. 38.)

CHAPTER 1

INTRODUCTION

Cancer is the uncontrolled growth of cells. [1] About 1,000 Americans die every day with the 100 or more diseases called cancer. Cancer causes over 16 percent of all U.S. deaths, making it the second largest killer (after cardiovascular diseases). Estimates of cancer's annual cost to the Nation run as high as $15 billion, of which some $3 to $5 billion represents direct care and treatment costs; the balance is loss of earning power and productivity.

Cancer mortality in the United States ranks somewhere in the middle of the worldwide range, but the rank of mortality from specific types of cancer varies markedly. Compared with other nations, the U.S. white population has the lowest mortality from stomach cancer and close to the highest from cancers of the colon and female breast. As shown in the table on page 3, the incidence rates of various cancers in the United States are expected to fluctuate between 1970 and 2000, including an 84-percent decrease in the incidence of stomach cancer and a 179-percent increase in lung cancer. The table also suggests some of the possible causes and means of preventing various cancers.

Available evidence suggests that environmental agents and social practices are largely responsible for variations in the occurrence of cancer in different populations. Although the extent to which man-made environmental chemicals are responsible for U.S. cancer rates is not precisely known, some scientists claim that external factors cause as much as 90 percent of all human cancer. National Cancer Institute (NCI) officials pointed out that this high estimate includes voluntary exposures to such carcinogens as cigarette smoke, which appears to be responsible for about 40 percent of all cancer in white males. NCI officials added that cancer attributable to occupational exposure and exposure to natural carcinogens is included in the 90-percent value.

NCI, 1 of the 11 National Institutes of Health, aims at reducing the occurrence of the major types of cancer in the United States to the level of the lowest ranking country for that type. Such a reduction would cut U.S. deaths from cancer by one-third.

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[1] More technically, cancer is a disease process characterized by the development of host-derived tissues which grow irreversibly in a manner uncoordinated with that of normal tissues and organs, which invade adjacent structures, which spread, and which persist after the stimuli are withdrawn.

Seven Federal agencies have principal authority for identifying and/or regulating cancer-causing chemicals 1/ (carcinogens) or the products in which they appear.

--NCI.

--National Institute of Environmental Health Sciences (NIEHS).

--National Institute for Occupational Safety and Health (NIOSH).

--Food and Drug Administration (FDA).

--Environmental Protection Agency (EPA).

--Occupational Safety and Health Administration (OSHA).

--Consumer Product Safety Commission (CPSC).

Their roles and responsibilities are discussed in chapter 2. Despite this wide base, no single agency or official has assumed a leadership role, and as a result, many unresolved issues have hampered effective public protection from carcinogens. This report discusses the impact of several of those issues, including

--what chemicals are tested,

--how tests are designed,

--how results are communicated, and

--what agencies consider when deciding on regulatory action.

This report is concerned with Federal agencies' efforts to protect the public from carcinogens. Other GAO reports dealing with more general effects of chemicals and other environmental factors are listed in appendix IV.

1/Throughout this report, the term "chemicals" will be used to refer to individual chemicals, compounds, and mixtures, unless otherwise noted.

Cancer Incidence: Expected Number, 1970-2000

Change in Rates, 1970-2000; Deaths, 1970

Site	New cases (incidence) (note a) 1970	New cases (incidence) (note a) 2000	Deaths 1970	Incidence year 2000 (percent change in rate) (note b)	Major causation	Means of prevention
Lung	81,000	295,000	62,000	179	Tobacco smoke. Air pollution (including on-the-job).	Stop smoking. Reduce pollution. Use less hazardous cigarette.
Large and small bowel	92,000	134,000	44,000	11	Intestinal flora? Heredity? Diet?	Viruses? Other insults. Identify susceptibles and eliminate their exposure.
Breast	82,000	111,000	30,000	4	Virus? Diet? Hormones? Genetic?	Vaccines. Identify susceptibles.
Pancreas	20,000	35,000	18,000	38	Diet? Virus? Other insults?	Identify etiology. Identify susceptibles.
Prostate	51,000	78,000	17,000	17	Hormones? Diet?	Identify etiology. Identify susceptibles.
Stomach	21,000	4,500	16,000	-84	Diet. Poor socio-economic conditions.	Diet modifications. Sociologic modifications?
Leukemias	20,000	32,000	15,000	26	Viruses. Radiation. Genetic.	Vaccines. Identify susceptibles and limit radiation.
Non-melanotic skin	376,000	585,000	5,000	20	Actinic rays. Genetic.	Limit radiation exposure. Identify susceptibles.
Miscellaneous	242,000	408,000	75,000	30	Multiple.	Identify extrinsic and intrinsic factors and modify them.

a/Based on data from Third National Cancer Survey, 1969-70. Cases in which the disease was confined to the site of origin without invading neighboring tissues (in situ) have been excluded.

b/Projected change in age-adjusted incidence rates (year 2000 compared to 1970), assuming the trend in rates noted from 1947 to 1969 continues to the year 2000.

Source: National Cancer Institute, Division of Cancer Cause and Prevention; Annual Program Review Document for Fiscal Year 1974.

CHAPTER 2

FEDERAL RESPONSIBILITY

The Federal Government attempts to protect the public from carcinogens through research and regulation. NCI sponsors most of the Government's research on cancer cause and prevention; NIEHS, NIOSH, and some of the regulatory agencies also conduct or sponsor such research. EPA is responsible for clean air and water and safe pesticides; OSHA sets and enforces standards to protect workers from safety and health hazards, including hazardous chemicals, in workplaces; FDA is responsible for the safety of foods, food and color additives, drugs, medical devices, and cosmetics; and CPSC has jurisdiction over every consumer product not covered by any other agency except those specifically excluded by the Consumer Product Safety Act.

Several other Federal agencies help to protect the public from carcinogens. Their activities, however, are generally initiated as a result of some other action taken by one of the principal organizations. Appendix V contains more information on these agencies.

RESEARCH AND REGULATORY AGENCIES

NCI--The National Institutes of Health attempt to improve the health of all Americans by sponsoring biomedical research activities. NCI is the largest institute, with appropriations for fiscal year 1976 of about $743 million. The National Cancer Act of 1971 (42 U.S.C. 282) was passed to strengthen NCI, mainly through increased authority and funding authorizations, to more effectively combat cancer. Among other things, the act authorized NCI's director to plan and develop an expanded, intensified, and coordinated cancer research program, encompassing programs of NCI, related programs of other research institutes, and other Federal and non-Federal programs. The National Cancer Program's ultimate goal is to develop the means for eliminating human cancer.

NCI established a research program on the causes of cancer in 1961, although it had previously supported such research. A more formal program dealing with chemical carcinogens (as opposed to other possible causes of cancer, such as viruses) was begun in 1968, and today NCI sponsors research to find out what causes cancer; who is likely to get cancer; how to study the causes of cancer; why, how, and where cells become cancerous; and what we can do to prevent cancer. In fiscal year 1974, NCI reported that it spent about $100 million researching environmental causes of cancer, of which

$9.5 million was spent on animal testing of suspected chemicals. The latter amount dropped to about $9.3 million in fiscal year 1975.

NIEHS--NIEHS is also part of the National Institutes of Health. Its mission is to (1) identify the chemical, physical, and biological factors in the environment that can adversely affect people, (2) contribute to an understanding of the mechanisms and manifestations of human diseases produced by these agents, and (3) provide the scientific basis for developing control measures by other agencies. NIEHS is particularly concerned with the effects of low levels of chemicals over long periods of time.

NIEHS officials said they generally avoided cancer research because of NCI's established role. Although NIEHS does not routinely test chemicals to determine their cancer-causing ability, it funded over 40 studies during fiscal year 1974 that dealt in some way with the carcinogenic effects of certain chemicals. For example, one study involved the effect of various environmental chemicals on lung cancer in hamsters.

NIOSH--Under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651), NIOSH conducts and sponsors research and reviews literature to develop criteria for protecting workers from occupational safety and health hazards. A major NIOSH responsibility is to provide OSHA with proposals and supporting data (criteria documents) for new or improved occupational safety and health standards. In fiscal year 1974 NIOSH funded about 225 research projects (contracts, grants, and interagency agreements) at a cost of about $16.3 million; of these only 4 dealt specifically with occupational carcinogenesis. According to the Department of Health, Education, and Welfare (HEW), NIOSH has increased its efforts in occupational carcinogenesis research and in fiscal year 1976 will spend about $7 million.

FDA--The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) gives FDA authority to protect Americans from foods that are not pure, wholesome, and safe to eat; from drugs and therapeutic devices that are not safe and effective when used as intended; and from cosmetics that are not safe or made from appropriate ingredients.

The law is designed to protect consumers by requiring manufacturers to prove the safety of drugs, food additives, and color additives before they can be marketed. Food additives must be "generally recognized as safe" or manufacturers must scientifically prove their safety for their intended use to FDA's satisfaction before marketing them. FDA checks to see that residues of pesticide chemicals in foods do not exceed tolerance levels 1/ set by EPA.

Cancer is a specific health effect for FDA to consider only when judging the safety of food or color additives. The Delaney Clause, a 1958 amendment to the Federal Food, Drug, and Cosmetic Act, requires FDA to ban the use of a food additive when:

> "it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

A 1960 amendment applied the language of the Delaney Clause to color additives used in foods, drugs, or cosmetics. Further amendments in 1962 allow carcinogenic chemicals to be used in animal feeds but only if no residue of the chemical can be found by an approved method in food products taken from the animal and if the additive does not adversely affect the animal.

FDA and EPA jointly sponsor the National Center for Toxicological Research to study the biological effects of potentially toxic environmental chemicals. The Center's principal mission is to develop better methods to evaluate the degree of toxicity of chemicals.

EPA--EPA was established in 1970 to centralize Federal activities for, among other things, controlling pesticides, air and water pollution, and drinking water quality.

The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135) requires pesticide manufacturers to prove the safety of their products to EPA before selling them. If a pesticide remains in or on a food product, EPA has to set a tolerance for the pesticide. If the pesticide is a carcinogen, EPA must set a tolerance or exempt the pesticide from the tolerance requirement.

The Federal Water Pollution Control Act (33 U.S.C. 1251) requires EPA to publish a list of toxic water pollutants and set limits for their discharge into waterways. The act also requires EPA to publish water quality criteria which would

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1/Tolerance levels are the maximum levels of pesticides that may legally remain in food.

provide the basis for State water quality standards. The recently enacted Safe Drinking Water Act (Public Law 93-523) requires EPA to set drinking water standards to protect the public health and provide an esthetic water supply. In setting the standards, EPA must consider recommendations from the National Academy of Sciences on the maximum level of contaminants that EPA should allow in drinking water.

The Clean Air Act (42 U.S.C. 1857) authorizes EPA to develop air pollutant standards in seven categories, including primary ambient air quality (to protect the public health), secondary ambient air quality (to protect the public welfare), and hazardous air pollutants (to prevent increased death or illness). EPA can require manufacturers of fuels or fuel additives to conduct tests to assess the chemical's carcinogenic potential.

EPA also has the authority to set standards for protecting the general environment from radioactive materials. The Nuclear Regulatory Commission and the Energy Research and Development Administration are primarily responsible for developing, implementing, and enforcing radiation standards for individual nuclear facilities.

EPA research is conducted through grants, contracts, and agreements with several sources as well as through its own laboratories. In fiscal year 1975 it spent $170 million for research and development of pollution processes, effects, and control technology. The research is not usually concerned specifically with carcinogenesis but with the whole range of possible adverse health effects from the environment.

CPSC--In 1972 the Consumer Product Safety Act (15 U.S.C. 2051) created CPSC as an independent regulatory agency to reduce the unreasonable risk of injury associated with consumer products. CPSC became operational in May 1973.

In addition to the new responsibility under the 1972 act, CPSC assumed responsibility for several existing consumer protection statutes, including the Federal Hazardous Substances Act (15 U.S.C. 1261). Under its general authority, CPSC can perform research necessary to regulate carcinogens in consumer products. CPSC also has the authority to ban or regulate the marketing of consumer products which can cause personal injury or illness.

Specifically excluded from CPSC's authority under the Consumer Product Safety Act are (1) articles not normally considered consumer products, (2) tobacco and tobacco products, and (3) certain products, such as drugs, pesticides, and motor vehicles, regulated under other Federal laws.

In fiscal year 1975 CPSC awarded 104 contracts for about $6 million. An official of CPSC's Bureau of Biomedical Sciences said that five of the contracts, costing about $1.1 million, related in some way to carcinogens and consumer products. Although CPSC emphasizes hazards and injuries rather than illness, one of the agency's objectives is to develop methods for testing carcinogens in consumer products.

OSHA--OSHA sets and enforces occupational safety and health standards, which pertain to a wide range of areas, such as farm vehicles and a chemical worker's exposure to a carcinogen. OSHA cannot ban production or use of hazardous chemicals but can protect a worker from exposure to them. The Secretary of Labor can, through order of the U.S. district courts, restrain employers from exposing employees to imminent dangers.

BURDEN OF PROOF

Several sources indicate that almost 2 million chemical compounds exist today and that about 250,000 new compounds are created annually. About 300 to 500 new compounds, some of which may be carcinogenic, get into the environment and into commercial use each year, and for most of them no Federal authority requires that they be proved safe before they are used.

Protecting the public from carcinogens depends greatly on (1) where the burden of proving safety rests and (2) whether the proof must be established before the public can be exposed. Before manufacturers can begin marketing drugs, pesticides, and food and color additives, they must prove such products are safe. The burden of proof remains with the manufacturers even after they receive initial Federal approval. For example, FDA needs only to gather information indicating an association between a marketed drug and an adverse reaction; the manufacturer retains the burden of proving the drug's safety in light of the new information.

In contrast, the burden of proving the health hazards of chemicals in other products rests with the Government. Because manufacturers can market these products without proving their safety, the public can be exposed to such chemicals before the Government can prove their harm. EPA must prove which chemicals already in the air and water are health hazards; FDA must prove that chemicals in cosmetics are injurious to health; OSHA must prove what levels of chemical exposure in workplaces threaten workers' health; and CPSC must prove the health hazard of chemicals used in consumer products.

An exception to the general burden of proof rule may be when an agency is petitioned to regulate carcinogenic chemicals, in which case the burden of proof rests with the petitioners. For example, in December 1975 CPSC was petitioned to regulate certain fluorocarbons in consumer products because of a potential increased risk of skin cancer. CPSC denied the petition because the petitioners had not proved the health hazard of the fluorocarbons.

As a result, the public may be exposed to certain chemicals for a long time before the Government regulates them because of their carcinogenicity. For example, workers had been exposed to beta-naphthylamine for more than 50 years by February 1974, when OSHA regulated it because of its carcinogenicity.

PENDING AND SUGGESTED LEGISLATION

The proposed Toxic Substances Control Act (S. 3149), passed by the Senate on March 26, 1976, states that adequate data should be developed with respect to chemical substances and mixtures concerning their effect on human health and the environment and that such data development should be the responsibility of those who manufacture or process such substances. The Senate version would require manufacturers of new chemicals to notify EPA of the existing data concerning environmental or health effects of the new chemical at least 90 days before first manufacturing it. Additionally, if EPA determines that new or existing chemicals may present an unreasonable risk to health or the environment, or if EPA lacks sufficient data to judge their environmental or health effects, it may require the manufacturer to make safety tests. Such tests may be made to detect the chemical's cancer-causing potential, at EPA's discretion. The act would not apply to pesticides, drugs, or food and color additives which now receive premarket safety testing. As of May 27, 1976, the House Interstate and Foreign Commerce Committee had not passed this bill.

The Surgeon General's report on the health consequences of smoking identifies cigarette smoking as the major cause of lung cancer. About 72,000 people died of lung cancer in the United States in 1973. On June 27, 1974, the Secretary of HEW recommended that the Congress consider legislation to set maximum permissible levels for hazardous ingredients--such as tar and nicotine--in cigarettes. HEW officials told us, however, that as of April 1, 1976, HEW had not introduced such legislation but that two bills dealing with this subject had been introduced--S. 2248, which would require the Federal Trade Commission to establish acceptable levels of tar and nicotine in cigarettes; and S. 2902, which would tax cigarettes based on their tar and nicotine content and use these tax revenues for increased support of biomedical research.

CONCLUSIONS

The Congress has given NCI, NIOSH, and NIEHS broad authority to conduct or sponsor research to identify carcinogens. NCI has done most of the research. The regulatory agencies do little research on their own to identify carcinogens, but manufacturers of drugs, pesticides, and food and color additives must do research to prove their products' safety before these products can be marketed.

For chemicals that reach the public through other products and through the environment, however, the Government must initiate a regulatory action to remove them from the market. Cancer-causing chemicals can be controlled--either by safety testing before the chemical is marketed or by Government testing and regulation after it is marketed.

The Congress is considering toxic substances legislation to require premarket safety testing of chemicals which may present an unreasonable risk to health or the environment. Enactment of the Toxic Substances Control Act could shift the burden of proving a new chemical's safety to the manufacturer by requiring such proof before the chemical could be marketed. Enactment, we believe, would improve public protection from carcinogens.

Because tobacco and tobacco smoke are known human carcinogens (see app. VI), the Congress should request HEW to prepare a study showing the available options to regulate tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate. The Congress should then consider, as the Surgeon General has recommended, giving HEW or some other appropriate agency the specific authority to regulate tobacco and tobacco products.

CHAPTER 3

NEED FOR A FEDERAL POLICY CONCERNING CARCINOGENS

Federal agencies have problems accepting and applying the results of animal tests to people because (1) NCI has only recently developed minimum testing guidelines for determining a chemical's carcinogenicity and other agencies have not officially adopted them as a basis for carcinogenicity testing and (2) there are no scientific principles to help Federal agencies apply animal test results to humans. As a result, some carcinogens are not regulated at all while others are regulated differently by the different regulatory agencies. All agencies responsible for protecting the public from carcinogens should, we believe, cooperate to develop a uniform policy for identifying and regulating carcinogenic chemicals and the products in which they appear. The policy should also deal with such issues as under what conditions regulatory agencies will allow public exposure to carcinogens.

EFFECTIVENESS OF PREMARKET AND POSTMARKET TESTING

Premarket testing

Although some legislation discussed in chapter 2 is intended to assure the safety of all pesticides, drugs, and food and color additives before they appear in commercial use, not all chemicals used in these products have received the kind of long-term tests that experts agree are needed to detect any cancer-causing potential.

Before requiring manufacturers to conduct long-term animal tests for drugs, FDA considers the type of exposure people will get (one-time dose or prolonged use) and the number of people expected to be exposed.

The Federal Fungicide, Insecticide, and Rodenticide Act requires manufacturers to test and prove to EPA that their pesticides are not harmful to human health. Since 1963, when the Department of Agriculture administered the act, manufacturers of pesticides which leave residues on foods have been required by the administering agency to conduct long-term tests to detect carcinogenic potential. In safety evaluations for 30 randomly selected pesticides with tolerances for residues on foods, we found that, of the 36 chemicals used in those pesticides, 7 did not receive the appropriate long-term testing. 1/ EPA officials said required safety data may not be available because (1) the pesticide was approved before 1963, (2) later EPA reviews were inadequate, or (3) the data could have been submitted but later lost during moves or reorganization.

Unintentional food additives

As discussed on page 6, the Federal Food, Drug, and Cosmetic Act requires that manufacturers of food additives prove their products' safety to FDA and that FDA disapprove any food additive that, when properly tested, is shown to cause cancer in animals or humans. The act covers both intentional and unintentional food additives. According to the legislative history of the act, examples of these additives are "substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."

In discussing the concept of safety in regulating food additives, a Senate report on 1958 amendments to the act (S. Rept. 2422, 85th Congress) stated:

> "Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary [of HEW] include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count."

Although FDA's Deputy Chief Counsel advised us that the Federal Food, Drug, and Cosmetic Act requires manufacturers of food additives to test for carcinogenicity, FDA's Associate Chief Counsel for Foods advised us that the act only requires that safety be assured before FDA approval.

According to officials in FDA's Division of Food and Color Additives, all intentional food additives must receive long-term tests to detect carcinogenicity before FDA will approve them. Intentional additives are to (1) improve nutritional value, (2) maintain freshness, (3) improve esthetic appeal, or (4) aid in processing.

1/See the GAO report to the Congress: "Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?" (RED-76-42, Dec. 4, 1975), p. 7.

Unintentional additives are used mainly in packaging foods and, according to the FDA officials, receive long-term testing only when the consumer would be exposed to more than 1 or 2 parts per million of the additive in the food unless FDA had valid reasons to suspect that the additive might be carcinogenic. FDA officials explained that the long-term tests were very expensive, and because virtually none of the unintentional additives migrate from the packaging material to the food, the amount of the additive which may be ingested is virtually nil. FDA's principle in this regard is the higher the anticipated human exposure, the greater the amount of toxicological data required to assure human safety.

One official said that FDA had approved about 10,000 unintentional food additives, but he could not readily determine how many of the 10,000 had not received long-term testing. We noted that FDA has approved a few suspected carcinogens for adhesives that are used for packaging, transporting, and holding food.

In commenting on our report (see app. I), HEW stated that, although extending carcinogenicity testing to indirect food additives that have only remote possibilities of risk might be reassuring, it does not foresee any benefit to the public great enough to justify the substantial costs of such a policy.

We noted, however, that an April 1970 report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens recommended that:

--No level of exposure of a chemical carcinogen should be considered toxicologically insignificant for humans.

--No chemical substance should be assumed safe for human consumption without proper negative lifetime biological assays of adequate size.

Under this view, FDA would be unable to assure the safety of food additives that do not receive long-term testing.

Postmarketing testing

Scientists believe that most cancer is caused by chemicals already in the environment. As discussed on page 8, the Government must initiate regulatory action to control potentially carcinogenic chemicals that appear as air or water pollutants, as occupational health hazards, or in consumer products.

Although several Federal agencies conduct and sponsor some long-term chemical testing, except for NCI they do not routinely test large numbers of existing chemicals for carcinogenicity. NCI's tests take about 3 years from initial chemical selection to final reporting. NCI spends from $150,000 to $205,000 to test each chemical, and at its fiscal year 1975 funding level it can add about 50 to 60 chemicals to its testing program each year.

IDENTIFICATION OF CARCINOGENS

Many chemicals have been tested for their carcinogenicity in animals, but Federal agencies and non-Federal organizations have trouble identifying which chemicals cause cancer in humans.

NCI

NCI sponsors research to detemine whether chemicals cause cancer. At January 1, 1975, NCI had 550 chemicals in its test program. NCI also reviews the scientific literature to identify carcinogens. It has compiled a list of 36 chemicals or chemical compounds (see app. VI) which definitely cause cancer in humans. NCI said that the scientific community generally accepted these chemicals as definitely being human carcinogens, yet the public can be exposed to at least 32 of the 36 substances. At our request, an NCI staff member classified the exposure hazard of the 36 substances into the following 6 categories. (See app. VII.)

Controlled or restricted use; protection requires technical surveillance	15
Voluntary; personal choice by the user	3
Poorly controlled	14
Prescribed by physician	1
Used in laboratory only	2
No longer produced in significant quantities	1
	36

Although the NCI staff member stated that the use of 15 of the known human carcinogens is controlled or restricted by regulatory agencies, the public is not, we believe, adequately protected from some of these chemicals because Federal regulations neither ban their use nor cover all means of public exposure. Many cancer experts--including the 1970 ad hoc committee of the Surgeon General--agree that a safe level of a carcinogen cannot be established and that any exposure may cause cancer. Two human carcinogens which the NCI staff member classifies as being controlled or restricted--asbestos and benzidine--are discussed in more detail on pages 23 to 25.

The chief of NCI's carcinogen bioassay and program resources branch stated that, of all chemicals tested by NCI contractors between 1962 and 1973, 214 were carcinogenic in animals. The public is exposed to some of these chemicals.

An NCI official said that the traditional method of releasing test results is through publication in scientific journals and through symposia but that this method has worked poorly. NCI is initiating a technical reporting series that would contain certain information on each chemical's exposure, use, and production, as well as a detailed explanation of test procedures and results. Chapter 4 contains a detailed discussion of NCI's role in identifying carcinogens.

Public Health Service

The Public Health Service--a part of HEW which includes the National Institutes of Health, FDA, NIOSH, and several other operating agencies--publishes general information on any animal carcinogenicity experiments of which it is aware. An NCI official said that the publications contained 6,000 chemicals. Although the Public Health Service does not indicate whether a chemical is a carcinogen but merely recaps information provided in published studies, NCI officials advised us that about 1,000 of the 6,000 have been reported in the literature to cause cancer in animals; many of these reports, according to NCI, appear to be based on inadequate data.

NIOSH

NIOSH conducts and sponsors research and reviews existing research literature to develop criteria for OSHA standards. NIOSH has developed and published a list of all known toxic substances. In its 1975 edition, NIOSH reported that information was included on the carcinogenicity of 1,500 chemicals.

World Health Organization

The International Agency for Research on Cancer, a part of the World Health Organization, publishes monographs on its evaluation of the carcinogenic risk of chemicals but makes no recommendations for preventive measures.

In March 1975 the agency reported that, of 196 compounds evaluated, 151 (77 percent) were carcinogenic. Of the 151, 17 were associated with human cancer, 93 were definitely carcinogenic in animals, and 41 had a limited carcinogenic effect on animals.

The type of exposure to the 17 human carcinogens was occupational for 14, medicinal for 2, and dietary for 1. In addition, some of the 93 chemicals found to be definitely carcinogenic in animals are produced in very large quantities.

Regulatory agencies

At the time of our review, the regulatory agencies--FDA, EPA, OSHA, and CPSC--did not maintain lists of carcinogens but had from time to time regulated chemicals because of their carcinogenicity. For example, from 1950 to 1974 FDA banned 14 food and color additives because of a finding or suspicion of carcinogenicity. In 1973 EPA published a list of toxic water pollutants and included benzidine because it was a carcinogen. When EPA proposed drinking water guidelines in 1974, it listed toxic chemicals, including arsenic and chromium, which it acknowledged as suspected carcinogens. In 1974 OSHA regulated the use of 14 chemicals 1/ in the workplace and CPSC banned the use of vinyl chloride in self-pressurized containers because the chemicals were carcinogenic. The regulatory agencies have taken or proposed action on several other carcinogens as well.

By November 1975 OSHA had developed a priority list of 220 chemicals to be used in its standard development activities; of the 220, OSHA indicated that 50 were suspected carcinogens. An OSHA official stated that OSHA wanted NIOSH to use this list in developing criteria documents.

PROBLEMS IN IDENTIFYING HUMAN CARCINOGENS

As previously stated, NCI considers that at least 1,000 chemicals have been reported to cause cancer in animals. Federal agencies have trouble determining which chemicals also pose carcinogenic threats for people. Some of the problems are that:

--Federal agencies have not been able to adopt a set of general principles concerning environmental carcinogenesis.

1/On December 17, 1974, the U.S. Court of Appeals for the Third Circuit vacated the standard for 1 of the 14 chemicals (4, 4'-methylene bis(2-chloroaniline)) because OSHA made a procedural error in formulating the standard. The court also vacated the standards of the other 13 chemicals as they applied to research laboratories.

--NCI has only recently developed minimum testing guidelines which other agencies have not yet officially adopted as a basis for carcinogenicity testing.

--When experimental data are available, they may not be as complete or appropriate as the agencies would like.

--The limited state of the art does not allow scientists to accurately predict human response to chemicals on the basis of animal test results.

In addition, even though Federal agencies believe a chemical to be carcinogenic, legislation and court decisions may require them to consider factors other than public health when deciding whether and how to regulate carcinogenic chemicals.

Principles of carcinogenesis

The April 1970 report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens discussed the problems of environmental exposures to chemicals and the scientific criteria for evaluating carcinogenic hazards. The report, which is not HEW policy, deals with evaluating animal test results, problems in establishing a safe level of exposure, need for proper lifetime tests, and the principle of a zero tolerance for all exposures to chemical carcinogens. Several cancer experts restated some of these principles during administrative hearings on EPA's efforts to ban two carcinogenic pesticides--aldrin and dieldrin.

Representatives from six agencies met in August 1974 to discuss several areas concerning environmental carcinogenesis. According to the EPA representative, Federal agencies had a growing need to agree on a national policy, particularly in terms of risk-benefit considerations. As of April 1, 1976, however, no such policy had been developed. (See p. 32.)

Most recently, a subcommittee of the National Cancer Advisory Board is considering the general criteria for assessing the evidence for carcinogenicity of chemical substances, and NCI has chartered a new committee to review, evaluate, and interpret carcinogenicity data generated by the NCI testing program.

Minimum test guidelines

Because testing suspected carcinogenic chemicals on humans is neither ethical nor practical, scientists use animals. Experience with laboratory animals has shown that nearly all chemicals that are carcinogenic in people are also carcinogenic in animals. The way a test is designed--the number of animals and dose levels used, the length of the test, and other laboratory conditions--can directly affect the validity of the results and their value to regulatory agencies.

The more animals tested, the more statistically sensitive are the results. Similarly, the more species used, the greater is the assurance that the chemical, and not some other factor, caused the cancer. Also, the more test dose levels administered, the better a scientist can estimate the relationship between the dose and the animal response. Finally, the tests should be conducted over the animal's lifetime to better approximate human exposure.

NCI has developed standard testing guidelines to be used by commercial labs under NCI contracts to test environmental chemicals. NCI officials hope that these guidelines, issued in January 1975, will (1) make research results more comparable and more applicable to humans, (2) increase the tests' sensitivity, and (3) provide better data on which regulatory agencies can act. In addition to prescribing animal care standards, the guidelines call for at least 2 doses to be given to 50 animals of each sex and each of 2 species.

NCI has shared these guidelines with other Federal agencies and at least two of them--EPA and NIOSH--have provided for consideration of these guidelines in some of their test procedures. None of the agencies, however, has officially adopted the guidelines as a basis for carcinogenicity testing. Some agency officials even question the need for such guidelines, stating that each test should be designed individually. NCI believes that the guidelines describe many features which are common to all well-designed and properly conducted long-term animal studies and which need to be considered whenever a carcinogen test is planned or undertaken. Chapter 4 discusses some of NCI's problems in designing tests for use by regulatory agencies.

Before the NCI guidelines were developed, Federal agencies had no common guidelines for testing chemicals for their carcinogenicity. EPA had proposed guidelines for testing pesticides which called for 2 species, 3 dose levels, and between 25 to 50 animals of each sex and species per dose level. The National Academy of Sciences, under contract to EPA, recommended 2 rodent species, tested at several dose levels, with 40 to 50 animals of each sex surviving the highest dose. An international cancer group recommended at least two species (one of which should be a nonrodent mammal), one dose level 1/ (the highest dose tolerated by the animals), and enough animals to yield reasonably significant results. An FDA advisory committee suggested two rodent species tested at several dose levels, including one which would yield the most tumors, but did not say how many animals should be used.

Past regulatory actions have been based on results of research conducted under a wide variety of protocols. For example, the animal studies which conclusively linked vinyl chloride to a rare form of liver cancer included three species and seven dose levels. EPA on the other hand, proposing to limit the amount of benzidine in water, cited several studies to establish the carcinogenicity in animals and humans, but relied on an animal study which included only one species and one dose level through a route of administration (injection) not normally experienced by the public. 2/

Incomplete and inappropriate data

In some cases, the experimental data available to the regulatory agency is not as complete or appropriate as necessary. For example, the first link between vinyl chloride and cancer came in 1970 when a scientist reported tumors in rats exposed to extremely high doses of the chemical. Although these results were statistically valid, they were not viewed with alarm because the concentration of vinyl chloride was near the explosive limit and was not likely to be found in industrial situations. Similarly, a U.S. court of appeals denied EPA's proposed ban on dumping asbestos into the drinking water of Lake Superior because EPA could not prove that asbestos causes cancer when ingested. The carcinogenicity of inhaled asbestos has been documented for about 40 years.

Many chemicals have been reported to cause tumors in test animals, but regulatory agencies are hesitant to base any action on a single test. The 1970 report to the Surgeon General recommended that the test designs provide for reproducibility of results.

1/The international group considered it advisable to test more than one dose level.

2/As of May 27, 1976, this proposal was still pending. See page 24 for more information on EPA's proposed benzidine standard.

Predicting human response from animal tests

A critical problem in regulating carcinogens is trying to predict the human risk of exposure to small levels of chemicals solely on the basis of results of animal tests. The limited state of the art restricts scientifically sound regulation.

Conventionally, toxicologists have applied "safety factors" to animal test results and have assumed that an animal's reaction would not differ from a person's reaction by more than that factor. NCI's associate director for carcinogenesis has questioned whether this safety procedure can be applied to cancer risks because of the differences between cancer and other diseases.

The validity of tests on laboratory animals is most easily accepted when people are exposed to the chemical in the same way the test animals were. However, people are exposed to practically all chemicals at such low levels and for such long periods that an impractically large number of animals is needed to produce statistically valid results under those conditions. To further complicate the matter, a person's reaction to a chemical may be different than an animal's in terms of absorption, distribution and storage, metabolism, excretion and reabsorption, arrival at the site of action, and reaction with the biological receptor. One analysis of the state of the art for extrapolating results of animal tests to people concludes that there is a basis for comparing the median mouse to the median rat to the median dog to the median person. But the report warns of the greater difficulties in comparing the median animal to the not-so-average person.

At congressional hearings held in 1971 on "Chemicals and the Future of Man," concern was expressed about unduly frightening the public about adverse health effects from chemicals which had been commonplace. A House Appropriations Committee report gave some examples of how much of a banned substance a human would have to consume to receive amounts comparable to those given to experimental animals. The purpose of the examples, all of which dealt with carcinogenic food additives banned by FDA, was to translate abstract scientific studies into their real-life equivalents. According to the Committee's report:

--An adult would have to drink from 138 to 552 bottles of soft drink each day to get a comparable amount of cyclamate that caused cancer in mice and rats.

--A person would have to drink 250 quarts of vermouth each day to get a comparable amount of oil of calamus that caused cancer in rats.

--A person would have to drink 613 bottles of root-beer-flavored soda or eat 220 pounds of hard candy each day to get an amount of safrole comparable to that which caused cancer in rats.

Factors other than public health

The 1970 report to the Surgeon General stated:

> "Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man * * * [and] no level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents 'a safe level for man' cannot be established by application of our present knowledge."

Strictly applying this criteria, any chemical that causes cancer in animals would be presumed to cause cancer in people, regardless of level of exposure. But in some cases, laws require regulatory agencies to consider more than the carcinogenic risks of a chemical. When considering whether to approve a drug for marketing, FDA weighs its benefits against any safety risks. For example, some drugs used to treat cancer have also been shown experimentally to cause cancer. Certain drugs used to treat severe heart conditions are also carcinogenic. But FDA has determined that the immediate benefits from those drugs outweigh the potential risks.

Likewise, EPA considers the benefits and dangers to the public health and welfare from the use of pesticides. The Federal Environmental Pesticide Control Act of 1972 (7 U.S.C. 136) defines the "unreasonable adverse effects on the environment" of a pesticide as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

Since January 28, 1975, the Office of Management and Budget has required that agencies of the executive branch consider the inflationary impact of major legislative and regulatory proposals.

In revising its permanent standard for vinyl chloride, OSHA decided that no detectable level should be allowed in the workplace. After receiving industry views on the costs of compliance and a consultant's report of the economic impact of the proposed standard, OSHA raised the permissible level to 1 part per million. OSHA did not claim, however, that 1 part per million was a safe level of exposure to vinyl chloride.

Regulatory agencies also consider the practicality of their proposed actions, including the state of the art of analytical and detection equipment. When EPA developed a standard for asbestos in the air, an important consideration was the lack of satisfactory methods of measuring asbestos emissions. As a result, the asbestos standard was not written in terms of numerical values; instead, it limited visible emissions and required certain manufacturing techniques to reduce those emissions.

Federal agencies should consider these factors, when properly authorized and documented, in deciding on regulatory action against carcinogens. It is important for the public record that the documentation show the impact of the regulation on the public health, as well as on the other factors considered.

DIFFERENCES IN PUBLIC EXPOSURE TO CARCINOGENS

If a carcinogenic chemical is not banned, people may be exposed to it. Despite differences in the degree of such exposure, scientists have not proved that any exposure is harmless. Therefore, the public faces some risk of getting cancer when carcinogenic chemicals are not banned.

In its comments on this report (see app. I), HEW stated that, although it may be true that any exposure to a chemical carcinogen will cause cancer within the exposed population, the risk or probability that cancer will occur may very well be related to exposure levels. HEW said that, when exposure cannot be completely eliminated or the benefit is deemed to outweigh the risk from exposure, efforts must be made to estimate the upper limits of risk from specific levels of exposure using the best evidence obtainable by applying current research tools. HEW also recognized that current animal test procedures do not provide a quantitative assessment of the hazard to exposed human populations which would be required to resolve certain regulatory needs and questions.

We selected two chemicals that NCI has concluded to be known human carcinogens--asbestos and benzidine--to determine how the public is being protected from them. We found varying degrees of regulation over the two chemicals for various reasons.

Asbestos

Asbestos refers to a family of hydrated silicates that, when crushed or processed, separate into flexible fibers. Only six of the many asbestos minerals are of commercial importance.

Asbestos is used in over 3,000 products, and in 1972 over 800,000 tons were used in the United States. The regulatory agencies we reviewed all consider asbestos to be carcinogenic, but they regulate it differently.

On June 7, 1972, OSHA specified a numerical standard allowing some asbestos in the workplace. When NIOSH recommended the standard to OSHA, it conceded that the standard was based on the health hazards of asbestosis--a type of lung impairment--and not cancer, because there was insufficient information to set a standard to prevent lung cancer unless the standard was zero. This is consistent with NCI's belief that no level of exposure to a carcinogen should be considered safe for humans. However, on January 29, 1974, OSHA required that workers' exposure to 14 other chemicals it considered to be carcinogens be reduced to the maximum extent practical.

In October 1975 OSHA proposed lowering the permissible level of asbestos in most workplaces by 90 percent, recognizing the cancer risk of asbestos in the workplace and the technological and economic factors which, OSHA reasoned, had prevented such a regulation. If enacted, the new regulation would allow up to 0.5 fibers of asbestos per cubic centimeter of air in the workplace, averaged over an 8-hour work period.

On April 6, 1973, EPA developed a standard for asbestos in the air. The asbestos standard was not written in terms of numerical values, as is the OSHA standard for asbestos, but instead it limited visible emissions and required certain manufacturing techniques to reduce those emissions. An important consideration in the EPA standard was the lack of satisfactory methods of measuring asbestos emissions. Therefore, the standard was not based on a "safe" level of emission.

In January 1972 EPA tried to ban the dumping of asbestos into the drinking water of Lake Superior because asbestos was a carcinogen. A U.S. court of appeals denied this ban, however, because EPA could not prove asbestos causes cancer when ingested, although the carcinogenicity of inhaled asbestos has been documented for 40 years.

On September 28, 1973, FDA proposed several regulations to restrict the use of asbestos filters for drug manufacturfood, as a food or drug ingredient, or in food and drug packaging materials because of asbestos's carcinogenicity. On March 14, 1975, however, FDA decided to delay any final regulations because it stated that it could not prove that asbestos was present in those substances or that ingested asbestos caused cancer. FDA did, however, regulate the use of asbestos filters for manufacturing drugs used for injection in humans.

CPSC stated that asbestos is in a number of consumer products it is responsible for regulating, but it has not identified specific products. CPSC does not plan to regulate the use of asbestos in consumer products until considerable research is completed in the area.

The Government is studying whether ingested asbestos can cause cancer. Representatives from several Federal agencies developed a test protocol, and on June 30, 1975, NIEHS awarded two contracts for lifetime ingestion studies in rats and hamsters. The studies are to run for 4 years at an estimated total cost of about $2.9 million.

Benzidine

Benzidine occurs as white or slightly reddish crystals or leaflets or as a crystalline powder. Its domestic marketable production in 1972 was 1.5 million pounds. One source lists 361 dyes derived from benzidine and its salts. In addition, it appeared as a contaminant in workplaces before 1974 and as a toxic water pollutant. The suspicion that benzidine induced bladder cancer in workers was reported before 1940.

OSHA recognized both the animal and human carcinogenicity of benzidine and included it as 1 of the 14 chemicals it regulated in January 1974. Under these regulations, workers can only handle benzidine in a closed system--one where benzidine is not released into the work environment.

EPA recognized the potential for increased water pollution from benzidine and listed it as a toxic water pollutant in July 1973. In December of that year, it proposed an effluent standard to limit the discharge of benzidine into navigable waters.

EPA's proposed standard would have allowed each user of benzidine to dump up to 1 pound a day into the water. The amount each user could dump would depend on the characteristics of the waterway but not on the number of users dumping into that waterway. The method used to derive that standard was designed to determine a level of discharge which would result in an "acceptable level of risk" to people. The actual standard was derived by extrapolating animal test data using what EPA called conservative statistical methods. The method defined "acceptable level of risk" as less than one case of tumor induction per million people exposed over an entire generation to drinking water from supplies derived from waters contaminated with the maximum permitted concentration of benzidine. NCI's associate director for carcinogenesis commented on the specifics of EPA's supporting arguments for the standard, concluding that:

> "* * * an extremely inadequate, poorly documented experiment (carried out a quarter of a century ago) was used, without any attempt to further investigate its meaning, as a basis for the estimate of exposures to a large human population to one of the most effective presently known human carcinogens."

The NCI official referred to more recent NCI-supported studies, cited but not used by EPA to develop the proposed standard, which would have resulted in a lower standard for benzidine discharge.

Although EPA had not issued final regulations for benzidine as of May 27, 1976, it has been considering changing the proposed acceptable limit. Nevertheless, EPA maintains that:

> "* * * extrapolation methods should provide reasonable assurance that the true carcinogenic risk at the level identified in the standard will not be greater than the risk calculated at that level."

CONCLUSIONS

The public is being exposed to carcinogenic chemicals. In addition, new chemicals which may be carcinogenic are entering the environment because in some cases there is no premarket testing and in other cases the premarket testing that is done is insufficient. For example, not all premarket testing of food additives has included appropriate long-term tests that cancer experts agree are necessary to determine a chemical's carcinogenicity.

Even if all chemicals receive long-term tests, agencies may have problems accepting and applying the results of those tests to people because (1) NCI has only recently developed minimum test guidelines for determining a chemical's carcinogenicity and other agencies have not officially adopted them as a basis for carcinogenicity testing and (2) there are no scientific principles to help Federal agencies apply animal test results to humans. The appropriate Federal agencies should cooperate to resolve these issues in a manner consistent with the best available scientific knowledge.

As a result of the problems agencies face in identifying carcinogenic chemicals, some are not regulated at all while others receive inconsistent regulation. A uniform Federal policy on how to identify and regulate carcinogens is needed. Some of the issues which we believe should be included in such a policy are the

--information needed to protect the public,

--chemicals that should be tested,

--test guidelines that should be followed,

--way test results should be evaluated,

--feasibility of allowing exposure to carcinogens which would result in "acceptable levels of risk" for the public, and

--factors other than public health that should be considered.

CHAPTER 4

NCI'S PROGRAM FOR TESTING CHEMICALS

NCI is the only Federal agency that routinely tests large numbers of chemicals for carcinogenicity. Until recently, NCI's efforts had not given regulatory agencies much of the scientific data necessary to control or eliminate chemical carcinogens because (1) chemicals NCI tested were not always of the highest priority, (2) regulatory agencies did not agree on what type of data they needed to make decisions, and (3) NCI only recently developed a formal system to advise regulatory agencies on the carcinogenicity of chemicals tested.

The Congress, through the National Cancer Act of 1971, intended that the Director of NCI assume a leadership role in the Federal Government's efforts against cancer and coordinate other Federal and non-Federal programs. Recently, the NCI Director has been trying to involve the major Federal agencies in a coordinated program for identifying and regulating carcinogens.

THE CARCINOGENESIS PROGRAM

At the request of the National Advisory Cancer Council, NCI's principal advisory group, NCI developed a formal carcinogenesis program in 1968. This program evolved from other NCI activities that had been operating since 1961. The program is now composed of five coordinated approaches:

--Identifying and characterizing population groups at risk for different cancers.

--Identifying carcinogenic activity of selected chemicals by animal testing.

--Developing and selecting biological models for animal testing, for the characterization of carcinogenic processes, and for correlation with people.

--Identifying processes required for carcinogenic action of selected chemicals at target points for corrective measures in people.

--Developing, applying, and evaluating corrective measures for people and the environment.

NCI stated that in fiscal year 1974 it spent about $100 million on environmental carcinogenesis; of that about $38 million was for the carcinogenesis program, including

$9.5 million for animal testing contracts. In fiscal year 1975, NCI spent about $44.5 million for the carcinogenesis program, including about $9.3 million for animal testing contracts. Animal testing takes about 3 to 4 years from start to finish and costs from $150,000 to $205,000 for each chemical. On the basis of fiscal year 1975 funding, NCI can only add about 50 to 60 chemicals to the program each year.

CHEMICAL SELECTION

In view of NCI's fiscal constraints and the universe of untested chemicals, some of the chemicals being tested for carcinogenicity are of questionable priority because their production or use is limited or the public exposure is minimal. For example, in October 1971 an NCI contractor began testing Dulcin under a project designed to test chemicals commonly used in commerce and industry for their carcinogenicity. According to the contract, NCI hoped that the regulatory agencies would use the data to eventually eliminate those chemicals found to be carcinogenic. Dulcin is a non-nutritive artificial sweetener which FDA banned in 1950 because it caused liver tumors in rats. An NCI official explained that it is being tested to see if its carcinogenic effect can be inhibited by another chemical, arginine glutamate.

Another NCI contractor began to test Amiben, an herbicide, in December 1971. The contractor stated that the test required more of the chemical than the manufacturer normally produced in a year. NCI officials said that Amiben is a possible future replacement for existing herbicides.

Another NCI contractor is testing plant extracts and fractions, which are used as herbal folk remedies by geographically and culturally restricted societies, such as those found in South Africa, the island of Curacao, and some areas of South Carolina.

According to NCI officials, the carcinogenesis program as a whole has many needs for bioassay which may result in materials with limited human exposure being animal tested. As an example, they cited studies to establish how a chemical reacts in humans which frequently require testing substances which do not exist as such in the environment.

Selecting chemicals to test now involves a formalized system with input from several sources, including NCI, other Federal agencies, contractors, and other interested non-Federal groups. A committee reviews all the relevant data about a suggested chemical before deciding whether it should be tested. It does not, however, rank chemicals according to any priority. Because of the newness of the system, we did not evaluate its effectiveness.

NCI TEST DESIGNS

NCI should conduct its animal tests so that the appropriate regulatory agency can use the results to protect the public from carcinogens. As discussed in chapter 3, the regulatory agencies have not agreed on a set of standards, or minimum guidelines, for testing suspected carcinogenic chemicals. NCI officials believe that their animal testing guidelines, also discussed in chapter 3, will provide a scientific base for regulatory action on suspected carcinogens.

Other NCI officials stated that regulatory agencies might need more indepth and extensive studies to support regulatory action. One NCI official explained that the NCI testing program is merely a screening process to identify suspected carcinogens. He explained that NCI would have to spend twice as much time and money to make the types of animal tests that the regulatory agencies indicated would be needed. For example, NCI would have to test more dose levels to identify (1) any dose-response relationships and (2) what happens to the chemical in the body in terms of absorption, excretion, and metabolism.

Short-term testing

Proper animal testing of suspected carcinogens requires considerably more resources than NCI has made available. Therefore, researchers have become interested in using tissue culture to develop *in vitro* 1/models to screen selected chemicals. According to NCI officials, such procedures, compared to current animal testing, should require less time and money; require only small samples of test chemicals; and be as reliable, sensitive, and practical.

1/Literally, "within a glass," in this context referring to tests in which animal or human serum is extracted and grown in tissue culture, where it is exposed to test substances (viruses, chemicals). If carcinogenic, the substance will kill the cells or cause them to grow abnormally.

Other types of short-term tests 1/ are being considered to aid in identifying carcinogens. FDA uses in vitro testing to determine potential adverse effects of vaccines. FDA stated that it has found good correlation between in vitro and animal tests when using viruses but not chemicals. NCI has assigned a high priority to studying these short-term test systems. It hopes that a battery of these tests can be developed and validated by 1980.

In addition to supplementing the animal tests, NCI hopes the short-term tests can soon be used as "prescreens" to help select chemicals for the animal tests.

DISSEMINATION OF INFORMATION

When the animal tests are completed, NCI does not evaluate the human cancer risk of the chemicals tested. Rather, NCI scientists usually view their role as that of providing hard data from the experiments and letting others draw their own conclusions.

As a result of our discussions with NCI officials in July 1974 concerning dissemination of research results to regulatory agencies, NCI developed a "memorandum of alert" to notify the agencies of positive carcinogenic findings before the conclusive test results are available. In March 1975 this was used to notify EPA, FDA, and NIOSH of the carcinogenic hazards of trichloroethylene, a chemical used mainly as a degreasing agent in the metal industry and as a solvent and dry cleaning agent in the clothing industry. It is also used to extract certain substances from foods; for example, to remove caffeine to produce decaffeinated coffee. More than 600 million pounds of the chemical are produced in the United States each year; as of June 1, 1975, none of the involved regulatory agencies had acted on the "memorandum of alert" to further regulate the chemical because they did not have conclusive results.

1/These include an in vivo-in vitro test in which pregnant animals are injected with test chemicals, the embryo is removed, and the embryo cells are grown in culture. If the cells become malignant, they are reimplanted in another animal to develop into tumors. Another short-term test being considered is a mutagenicity screen, by which a chemical's ability to induce genetic change can be easily determined. Because mutagenicity and carcinogenicity may be closely related, researchers hope this screen will detect carcinogens as easily as mutagens.

According to an NCI official, the normal method of releasing test results in journals or at symposia had created problems. NCI has therefore proposed a technical reporting series to contain comprehensive information on each chemical's exposure, use, and production, as well as a detailed explanation of test procedures and results. NCI issued such a report on trichloroethylene in February 1976.

NCI COORDINATION EFFORTS

Section 407 of the National Cancer Act of 1971 requires the NCI director to develop a cancer research program that would be coordinated with related programs of the other research institutes and other Federal and non-Federal programs. With regard to cancer-causing chemicals, NCI has (1) sponsored the Interagency Collaborative Group on Environmental Carcinogenesis, an informal group of middle-management officials of several Federal agencies, (2) participated in HEW's Committee to Coordinate Toxicology and Related Programs, (3) met with the heads of five other agencies concerned with environmental and chemical carcinogenesis, and (4) organized a formal Interagency Coordinating Committee for the National Cancer Program. NCI has also provided general advice to the Congress; other Federal agencies; and representatives of industry, consumer groups, the news media, and the public on cancer-causing substances.

These efforts have been useful but have failed to bring about a uniform Federal policy on chemical carcinogens or achieve the degree of consistency that would give all segments of the public the same protection from carcinogens. As shown in chapter 3, workers' exposure to asbestos and benzidine is controlled, but the public may be exposed to the chemicals in consumer products, the air, or the water.

Interagency Collaborative Group on Environmental Carcinogenesis

This group was set up in January 1973 to serve as a technical discussion group of operating-level agency officials. An NCI official serves as chairman. The group represents 18 agencies but is not chartered, has no authority, and does not make recommendations to the agencies.

HEW Committee to Coordinate Toxicology and Related Programs

HEW's Assistant Secretary for Health set up this group in July 1973 to provide for information exchange, coordination, resource-sharing, and advice-giving by HEW agencies conducting toxicological research. The Committee, which has nine member agencies, is headed by the NIEHS Director and has addressed a variety of issues, some relating to carcinogenicity.

Group of six agency heads

NCI convened this group in August 1974 to discuss problem areas of environmental and chemical carcinogenesis. The following agencies were represented: NCI, NIOSH, FDA, EPA, 1/ the National Center for Toxicological Research, and the Center for Disease Control (an HEW agency responsible for providing leadership and direction in the prevention and control of diseases). At that meeting, the agency heads decided to let EPA develop a national policy statement on environmental carcinogens. As of April 1, 1976, a policy statement had not been developed (although one had been drafted), and the group had not met again.

Interagency Coordinating Committee for the National Cancer Program

This group was chartered in December 1974 to assist the NCI Director in coordinating Federal cancer research programs by (1) providing for information exchange, (2) reviewing information systems, (3) preventing unnecessary duplication of effort, and (4) promoting joint-funded projects. It consists of 18 members--9 from within HEW and 9 from other Federal agencies, including FDA, the National Center for Toxicological Research, NIOSH, and EPA. As of April 1, 1976, its only meeting, held on November 10, 1975, had been a briefing by NCI personnel on all NCI activities.

CONCLUSIONS

Because NCI is the only Federal agency that routinely tests large numbers of chemicals for their carcinogenic potential and because of its large commitment of time and money to each chemical being tested, it should be certain that the most important chemicals in terms of use, production, and exposure are tested first. NCI has recognized this problem and established a new chemical selection process which became operational during our review.

We recognize the other aspects of NCI's carcinogenesis program and the need to answer basic questions on cancer causation, but the routine testing of suspected chemicals to determine their carcinogenicity is a distinct and necessary NCI function.

1/EPA was respresented by two senior science advisors.

The key to the set of guidelines a lab will follow when testing for a chemical's carcinogenicity should be the minimum requirements of the agency responsible for regulating that chemical. But because the regulatory agencies have not agreed on a set of standards or minimum testing guidelines, research agencies cannot be sure that the regulatory agencies will act on their results.

NCI should conform its testing guidelines, to the extent possible, to the needs of the regulatory agencies.

CHAPTER 5

CONCLUSIONS, AGENCY COMMENTS AND OUR EVALUATION, RECOMMENDATIONS, AND MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress has given the Federal regulatory system the authority to protect the public from any proven carcinogen. In some cases, such as those involving pesticides, that authority is exercised before the carcinogens can be marketed; in other cases, such as those involving air or water pollutants, the Government acts after the carcinogen is in the environment.

Unfortunately, the Federal regulatory system has only achieved partial success because (1) Federal agencies have not developed a uniform policy on how to identify carcinogens, (2) most regulatory actions can be taken only after the carcinogens are in the environment or commercial use, and (3) Federal interagency coordination has not achieved agreement among the agencies charged with the identification and control of public exposure to carcinogens.

The regulatory agencies which approve chemicals as safe on the basis of manufacturers' tests do not require that all chemicals be tested for carcinogenicity. Therefore, some commonly used food and color additives, drugs, and pesticides may be carcinogens.

Although many chemicals are considered as potential human carcinogens because of their effects on animals, regulatory agencies are usually hesitant to remove them from the environment or even to limit their use. Much of this caution results from the lack of agreement among Federal agencies as to what findings should be considered valid indicators of human carcinogenicity. Federal agencies also have to be aware of economic, social, and other effects of their regulatory actions against chemical carcinogens.

Responsibility for identifying carcinogens and providing the scientific basis for their regulation rests mainly with NCI, although NIEHS, FDA, NIOSH, and EPA sponsor some animal testing. NCI's activities have been not only to identify carcinogens but also to answer many basic questions about how and why chemicals cause cancer. NCI's carcinogenesis program has selected some chemicals of questionable priority for testing.

The regulatory agencies themselves are not certain of the types of animal tests or general carcinogenesis principles they will accept. Because so many Federal agencies are involved in carcinogenesis research and regulation and because no overall Federal policy on these matters exists, Federal agencies have not consistently regulated known or suspected carcinogens or adequately acted on all means of public exposure to known carcinogens.

Public exposure to cancer-causing chemicals can be controlled--either by safety testing before the chemical is marketed or by Government testing and regulation after it is marketed. The problem has been to develop a system to select chemicals, properly test them in animals, evaluate the results in terms of people, and finally develop and implement regulations to protect the public.

If a carcinogenic chemical is not banned, people may be exposed to it. The exposure may be limited, but scientists have not proved that any exposure is harmless. Therefore, the public faces some risk of getting cancer when carcinogenic chemicals are not banned.

AGENCY COMMENTS AND OUR EVALUATION

In notifying HEW of our findings and conclusions, we proposed that the NCI Director, as head of the National Cancer Program:

--Provide leadership and coordination with other involved Federal agencies to establish a policy regarding the identification and regulation of carcinogens.

--Resolve the current issues, including (1) the information needed to protect the public from carcinogens, (2) the chemicals that should be tested, (3) the test guidelines that should be followed, and (4) the way results should be evaluated and used.

--Periodically reevaluate the policy, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters.

We also proposed that FDA have all approved and proposed food additives tested for carcinogenicity.

HEW generally disagreed with these proposals, stating that its Public Health Service has made important progress toward protecting the public from carcinogens since our review.

Set Federal policy

Although HEW agreed that a Federal policy on carcinogenesis is greatly needed, it disagreed that the NCI Director should set policy for regulatory agencies. HEW stated that NCI's major future challenge will be developing a procedural framework which meets the needs of the national program involving identification, risk evaluation, and prevention strategies for chemical carcinogens. HEW cited several interagency activities involving NCI staff that it believes promote better unerstanding of interagency concerns, which it hopes will lead to a more uniform Federal policy on regulating chemical carcinogens.

Although we did not intend that NCI unilaterally set regulatory policies or policies for other research agencies, we did intend that it be the focal point for seeing that a policy is established and that it more actively coordinate all Federal policies dealing with carcinogens so that these policies reflect the latest scientific advancements and afford maximum protection to the public. We believe that this role is in line with the NCI Director's responsibilities legislated by the National Cancer Act of 1971.

HEW stated that interagency activity will lead to a more uniform Federal policy on carcinogens but, as discussed on pages 31 and 32, past NCI coordination efforts have failed to bring about a uniform Federal policy. We believe that the Director of NCI should be made specifically responsible for developing a policy and that every agency with a role in protecting the public from carcinogens should be involved in developing that policy. Without an overall policy, there is no assurance that carcinogens will be consistently regulated by all agencies.

Resolve current issues

HEW stated that NCI is working to resolve the abovementioned issues by establishing a committee to evaluate data from its testing program, continually reviewing its procedures for selecting chemicals for testing, and developing minimum test guidelines for NCI and regulatory agencies. HEW stated that NCI will not and should not tell regulatory agencies how to use the test results.

According to its charter, NCI's data evaluation committee will be limited to reviewing for NCI's Director data from NCI's carcinogenesis program. The National Cancer Advisory Board subcommittee discussed on page 17 is developing general criteria for NCI's use in evaluating a chemical's carcinogenicity. We believe that these matters--the questions of what is tested, how the tests are performed, and how the results are evaluated--must be addressed and agreed upon by all agencies. For each agency to independently develop test guidelines and its own procedures for evaluating test results to determine whether a chemical is a carcinogen and the extent of regulation needed does not, in our opinion, provide for effective and consistent protection of the public. We believe that these issues are among the most important that must be resolved by a Federal policy.

Reevaluate the policy

Although HEW stated that NCI constantly reevaluates its policies, it did not comment on whether NCI should reevaluate a Federal policy once it is established. We continue to believe that responsibility for establishing and reevaluating the policy should rest with the Director of NCI.

Carcinogenicity testing of food additives

HEW stated that the Federal Food, Drug, and Cosmetic Act requires only that a food additive's safety be assured before FDA clearance. We agree with this statement but we do not agree that FDA can assure safety for unintentional additives when the additive migrates to the food and leaves a residue of less than 1 or 2 parts per million. In these cases, FDA usually does not require carcinogenicity tests. HEW also stated that, although extending carcinogenicity testing to unintentional food additives that have only remote possibilities of risk might be reassuring, it did not foresee any benefit to the public great enough to justify the substantial costs of such a policy.

Because the Delaney Clause implies that food additives that cause cancer in animals or humans are, per se, unsafe, we believe that the act intended FDA to consider cancer in assuring safety. According to the Surgeon General's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens (see p. 13), no level of exposure to a carcinogen should be considered toxicologically insignificant and no chemical should be considered safe for humans unless proper lifetime animal tests are negative. Based on these criteria, we do not believe that FDA can assure that all food additives are safe unless the additives receive carcinogenicity testing. To have the data necessary to assure safety, we believe FDA should require manufacturers to test all proposed food additives for carcinogenicity. Therefore, we believe that FDA should reconsider its policy of not requiring all food additives to be tested for carcinogenicity.

- - - -

OSHA and EPA also reviewed this report and had only technical comments. (See apps. II and III.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary require the NCI Director, as head of the National Cancer Program, to set a Federal policy on carcinogens. The policy, which should be developed with the cooperation, advice, and support of other involved Federal agencies, should address the scientific issues which have hampered effective public protection from carcinogens, including the

--information needed to protect the public,

--chemicals that should be tested,

--test guidelines that should be followed,

--way test results should be evaluated,

--feasibility of allowing exposure to carcinogens which would result in "acceptable levels of risk" for the public, and

--factors other than public health that should be considered.

We recommend that the NCI Director periodically reevaluate this policy, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters. We also recommend that the Secretary require FDA to have all approved and proposed food additives tested for carcinogenicity.

MATTERS FOR CONSIDERATION BY THE CONGRESS

Because tobacco and tobacco smoke are known human carcinogens (see app. VI), the Congress should request HEW to prepare a study showing the available options to regulate tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate. The Congress should then consider, as the Surgeon General has recommended, giving HEW or some other appropriate agency the specific authority to regulate tobacco and tobacco products.

The toxic substances legislation as introduced will require manufacturers to prove a chemical's safety before it is marketed rather than requiring the Government to prove that it poses a hazard after it is marketed. The Congress should also consider whether this change would, as we believe, improve Federal efforts to protect the public from carcinogens.

The Congress should especially emphasize its oversight responsibility for those Federal agencies and programs which would be affected by a Federal policy on carcinogens. Among the public issues that could be covered by such a policy would be whether the Government will allow people to risk getting cancer from these chemicals and, if so, how the Government will determine that risk in the absence of adequate scientific data.

CHAPTER 6

SCOPE OF REVIEW

We reviewed the activities of the major Federal agencies responsible for identifying potential cancer-causing chemicals and protecting the public from them. We also contacted officials of other Federal agencies involved in protecting the public from carcinogens. (See app. V.)

At the research agencies--NCI, NIOSH, and NIEHS--we reviewed ongoing and recently completed activities to find out what was being tested, how it was being tested, and what was being done with the results. At the regulatory agencies--FDA, EPA, OSHA, and CPSC--we reviewed their efforts to implement research findings to find out what information they used, what factors they considered, and how timely their actions were in regulating carcinogens.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

March 17, 1976

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Observations on Federal Efforts to Protect the Public from Cancer-Causing Chemicals." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES ENTITLED "OBSERVATIONS ON FEDERAL EFFORTS TO PROTECT THE PUBLIC FROM CANCER-CAUSING CHEMICALS"--B-164031(2)

General Comments

Although the report contends that Federal efforts to protect the public from carcinogens have achieved only partial success, we feel that PHS has made important progress toward this goal since the time of the GAO review. Beginning in fiscal year 1975, NIOSH greatly increased its efforts in occupational carcinogenesis. For fiscal year 1976, NIOSH has programmed approximately $7 million in this area. Also, all PHS agencies concerned with carcinogenesis have taken the initiative to coordinate their efforts in this field.

Those directing the Federal efforts toward controlling the exposure of the public to carcinogenic materials must recognize that, while it may be true that any exposure to a chemical carcinogen will cause cancer within the exposed population, the risk or probability that cancer will occur may very well be related to exposure levels. In those instances where exposure cannot be completely eliminated, or where the benefit is deemed to outweigh the risk from exposure, it is extremely important that efforts be made to estimate the upper limits of risk from specific levels of exposure using the best evidence that can be assembled through application of current research tools. It is anticipated that additional basic research on the cellular and molecular mechanisms of carcinogenesis will provide additional, fundamental information required for improving the quality of these estimates. As pointed out by the National Cancer Advisory Board (NCAB) Subcommittee on Environmental Carcinogenesis, the NCI should, and does, foster the development and validation of new and innovative analytic and bioassay techniques to meet the above needs. We recognize that current animal test procedures do not provide a quantitative assessment of the hazard to exposed human populations which would be required for a resolution of certain regulatory needs and questions.

We feel that epidemiologic investigations represent an essential component in cancer control. Constant vigilance must be maintained over the cancer rates among populations to detect trends which may indicate possible environmental etiology of cancer. These trends must be further investigated to identify the most likely agent or combination of agents which may be responsible. The separate efforts of the various health agencies such as CDC, through NIOSH and the Bureau of Epidemiology, and NIH, through NCI, are actively coordinated by the Assistant Secretary for Health through such committees as the Committee to Coordinate

Toxicology and Related Programs. Also represented as observers on these committees are other Federal agencies such as EPA and the Department of Defense.

GAO Recommendation

That the Secretary of HEW require the NCI Director, as the head of the National Cancer Program, to provide leadership and coordination with other involved Federal agencies to set policies regarding the identification and regulation of carcinogens.

Department Comment

We do not concur. The Director of the NCI is fully cognizant of his responsibility for providing leadership in the direction and coordination of Federal efforts in carcinogenesis and is not only firmly committed to this end but is already providing appropriate leadership and coordination. However, we do not believe that his role does or should include setting regulatory policies. Appropriately, setting such policies is within the purview of the appropriate regulatory agencies. The Director, NCI, concentrates on setting policy on scientific matters and advising the regulatory agencies on scientific and public health needs.

Within NCI, the establishment of the requisite procedural framework combining formal and informal arrangements at policy and working levels throughout the institute has received the highest priority and is now functional. Recent examples include the Interagency Coordinating Committee for the National Cancer Plan; the NCAB Subcommittee on Environmental Carcinogenesis, which is endeavoring to develop criteria for assessing carcinogenicity; and the NCI Committee for the Review and Evaluation of Carcinogenic Data, a newly approved advisory committee which will evaluate carcinogenesis data on a case-by-case basis as required based on need and priority. These activities are not intended to preempt or preclude specific undertakings, such as the NCI Temporary Committee to Evaluate Data on the Carcinogenicity of Cyclamates or the less formal effort involving NIOSH, NCTR, NCI, and industry to develop a protocol satisfactory for the evaluation of alpha and beta naphthylamines, or NCI's participation in the evaluation of current studies of diethylstilbestrol with NCTR, NIEHS, and FDA. The need for these specific undertakings will continue to exist, but the major challenge for the future will be the development of a procedural framework which meets the needs of the national program involving identification, risk evaluation, and prevention strategies for chemical carcinogens.

In the area of occupational carcinogenesis, NIOSH has the leadership role in applied research and criteria for standard development. Efforts are underway to accomplish a coordinated NIOSH-NCI approach.

Because of things such as benefit, risk factors, mechanisms of occurrence in the environment, and public needs and desires not all potentially carcinogenic materials can be regulated or controlled in identical fashion. Nevertheless, PHS recognizes the need for a Federal policy on carcinogenesis and has given it the highest priority. However, establishment of such a policy will take some time. Reprogramming, now in progress, requires restructuring, additional training of personnel, and the establishment of functional interlocking management systems among the agencies. The NCI has taken initiative in this direction as evidenced by its growing participation in many interagency functions. Such participation includes NCI staff membership on (1) the DHEW Committee to Coordinate Toxicology and Related Programs (CCTRP), including the chairmanships of CCTRP subcommittees; (2) FDA advisory committees; (3) the Science Advisory Board of NCTR including board subcommittees; and (4) the Science Advisory Board of EPA. It also includes the establishment of Interagency Collaborative Group on Environmental Carcinogenesis in collaboration with the Council on Environmental Quality to coordinate Federal efforts in the conduct of a prototype epidemiologic-demographic study of cancer etiology. Members of NCI, FDA, EPA, NIOSH, OSHA, and CPSC serve as advisors, consultants, and co-project officers on projects of mutual interest. These interactions promote better understanding of interagency concerns which we hope will lead to a more uniform Federal policy on the regulation of chemical carcinogens.

GAO Recommendations

That the NCI Director use the authority conferred by the National Cancer Act of 1971 to resolve the current issues, including (1) the information needed to protect the public from carcinogens, (2) the chemicals that should be tested, (3) the test guidelines that should be followed, and (4) the way results should be evaluated and used.

Department Comments

We partially concur in these recommendations. The Director, NCI, has taken steps to assure that information on potentially carcinogenic materials is made public at the earliest possible time. The mechanism for accomplishing this is the newly formed NCI Committee for the Review and Evaluation of Carcinogenic Data. Appropriate NCI officials will keep the committee informed of research results on testing suspected or potentially carcinogenic materials. The committee will hold public meetings at which information on suspected carcinogens will be discussed. After the completion of its meetings on a particular material, the committee will advise the Director, NCI, on what steps should be taken for distributing appropriate information to the public.

The NCI procedures used for selecting chemicals for testing are continually reviewed. The enactment by the Congress of the proposed Toxic

Substances Control Act (TSCA) (HR 76-64) with the amendment proposed by the Administration could affect the procedures used for selecting chemicals through providing a mechanism and fixing responsibilities for the screening of compounds. Future NCI activities in carcinogenesis testing may, in large part, be predicated on the provision of the proposed TSCA. The NCI is working closely with EPA and other Federal agencies (including FDA, NIOSH, and OSHA) in protocol development as it relates to possible requirements for industry testing.

The NCI has developed minimum test guidelines that have been at least partly adopted by regulatory agencies. However, these are only test guidelines, not specific protocols.

The Director, NCI, has used his authority to establish the NCI Committee on the Review and Evaluation of Carcinogenic Data which, on a case-by-case basis, will evaluate data and render advice on the use of such data. However, the NCI Director will not and should not direct the regulatory agencies on what use they will make of such data. He will provide them advice and data but they must make the appropriate decisions.

GAO Recommendation

The NCI Director should periodically reevaluate the policies, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters.

Department Comments

We concur. The NCI is constantly reevaluating its policies based on factors such as those cited by GAO.

[See GAO note, p. 47.]

[See GAO note, p. 47.]

GAO Recommendation

That the Secretary require FDA to have all approved and proposed food additives tested for carcinogenicity.

Department Comment

We do not concur. The report misinterpreted the Delaney Clause of the Federal Food, Drug, and Cosmetic Act as requiring that all food additives, both direct and indirect, be tested specifically for carcinogenicity. The Associate General Counsel for Foods did not advise the auditors that Section 409 of the Act requires testing for carcinogenicity in every instance. The law requires only that safety be assured prior to FDA clearance. The Delaney Clause applies only where "the additive in appropriate laboratory tests indicates a potential of inducing cancer," in which case the Commissioner requires "further testing (to) show that the additive would not produce cancer . . . ."

In determining the safety of the anticipated usage or presence of a compound in the food supply, FDA follows the principle that the higher the anticipated human exposure, the greater the amount of toxicological data required to assure human safety. This principle is directly applied in evaluating the safety of indirect food additives. Any packaging ingredient which has been demonstrated to be capable of migrating to food where the anticipated residue in food may be as much as or higher than 1 ppm usually leads the FDA to require a full scale toxicological review including lifetime feeding studies to investigate the potential for chronic toxicity and carcinogenicity of the compound in question. Below this level, but where there is still anticipated migration, 90-day feeding studies are required at the minimum for toxicological evaluations of safety. If there are valid reasons to suspect that the migrant may be carcinogenic, even under these insignificant levels of migration, judgment is applied as to whether or not lifetime carcinogenicity studies would be required or whether the substance should be treated as a suspect carcinogen and prohibited from usage.

Although it might be reassuring to extend carcinogenicity testing to indirect food additives that have only remote possibilities of risk, we do not foresee any significant benefit to the public to justify the substantial costs of such a policy.

GAO Recommendation

That, if, for any reason, the Consumer Product Safety Commission does not regulate high-tar cigarettes, the Congress may wish to request HEW to prepare a study for congressional consideration showing (1) the different options available to regulate tobacco and tobacco products and (2) the impact each option would have on the rising lung cancer rate in the United States.

Department Comments

The report places great emphasis on the need to clarify, by congressional action, governmental authority to control hazardous agents associated with cigarette smoking. The NCAB addressed this in a resolution to the President, dated November 27, 1974, in which the board recommended that limits be set for tar and nicotine content in cigarettes. Also, the Division of Cancer Cause and Prevention, NCI, recognizing the magnitude of the disease burden imposed by cigarette smoking, initiated a smoking and health program in 1970 with the objective of developing a less hazardous cigarette. These efforts are considered complementary to those leading to regulatory control of hazardous agents associated with cigarette smoking.

GAO note: Deleted comments relate to matters discussed in the draft report but omitted from the final report.

U.S. DEPARTMENT OF LABOR
Office of the Assistant Secretary for Administration
WASHINGTON, D.C. 20210

January 15, 1976

Mr. Gregory J. Ahart
Director
Manpower and Welfare Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Ahart:

This is in response to your letter of November 21, 1975, requesting comments on the proposed report entitled, "Observations on Federal Efforts to Protect the Public From Cancer-Causing Chemicals".

There are no recommendations to the Secretary of Labor in this report. Enclosed are specific comments on portions of the report for your consideration during preparation of the final report. [See GAO note.]

Thank you for this opportunity to review the proposed report and to furnish you with our comments.

Sincerely,

Fred G. Clark

FRED G. CLARK
Assistant Secretary for
Administration and Management

Enclosure

GAO note: These general and technical comments have been incorporated into the final report and are not included here.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

January 20, 1976

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Resources and Economic
Development Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

We received copies of the General Accounting Office's proposed report entitled, "Observation on Federal Efforts to Protect the Public from Cancer-Causing Chemicals" as transmitted with your letter of November 21.

In general, we feel that this is a balanced and accurate report of the National Cancer Institute's carcinogenesis bioassay program, and the relationship of this program to EPA and other Federal regulatory agencies.

I appreciate the opportunity you have given EPA to review and comment on this draft report prior to its publication.

Sincerely yours,

Alvin L. Alm

Alvin L. Alm
Assistant Administrator
for Planning and Management

GAO REPORTS DEALING WITH GENERAL EFFECTS OF CHEMICALS AND OTHER ENVIRONMENTAL FACTORS

1. "Use of Cancer-Causing Drugs in Food-Producing Animals May Pose Public Health Hazard: The Case of Nitrofurans" (report to the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, MWD-76-85, Feb. 25, 1976) discusses the lack of FDA action to determine whether residues of nitrofurans were present in food taken from treated animals.

2. "Need to Establish the Safety of Color Additive FD&C Red No. 2" (report to Senator Gaylord Nelson, MWD-76-40, Oct. 20, 1975) questions FDA's failure to resolve safety questions of a color additive which had been used for 15 years.

3. "Federal Pesticide Registration Program: Is it Protecting the Public and the Environment Adequately from Pesticide Hazards?" (report to the Congress, RED-76-42, Dec. 4, 1975) criticizes EPA's implementation of the Federal laws regulating pesticides, including the one that requires testing of proposed pesticides.

4. "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (report to Congresswoman Julia B. Hansen, RED-76-271, Oct. 23, 1974) provides information on the Government's procedures for testing pesticides, namely maleic hydrazide.

5. "Improved Federal and State Programs Needed to Insure the Purity and Safety of Drinking Water in the United States" (report to the Congress, B-166506, Nov. 15, 1973) deals with the chemical quality of certain water systems, concludes that potentially dangerous drinking water has been delivered to some consumers, and makes appropriate recommendations to EPA and HEW.

6. "Slow Progress Likely in Development of Standards for Toxic Substances and Harmful Physical Agents Found in Workplaces" (report to the Senate Committee on Labor and Public Welfare, B-163375, Sept. 28, 1973) concerns NIOSH's efforts to develop and recommend health and safety standards to OSHA for toxic substances in various occupational environments.

7. "Supervision over Investigational Use of Selected Drugs" (report to the Subcommittee on Reorganization, Research, and International Organizations, Senate Committee on Government Operations, B-164031(2), July 23, 1973) discusses, among other things, FDA's handling of proposed drugs which had caused cancer in animals.

8. "Environmental Protection Agency Efforts to Remove Hazardous Pesticides from the Channels of Trade" (report to the Congress, B-133192, Apr. 26, 1973) discusses EPA's suspension and cancellation procedures for hazardous pesticides.

SECONDARY AGENCIES INVOLVED IN CARCINOGEN REGULATION

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service--monitors the quality of meat, poultry, and egg products under standards set and enforced by EPA and FDA.

Agricultural Research Service--performs various research relating to carcinogens, including tests on meat, poultry, and egg product samples provided by the Animal and Plant Health Inspection Service and research involving mycotoxins.

DEPARTMENT OF COMMERCE

National Bureau of Standards--develops and evaluates measurement methods so that regulatory standards may be accurately quantified and enforced. The Bureau's Programmatic Center for Consumer Product Safety provides technical assistance to CPSC under a working agreement between the two agencies.

DEPARTMENT OF DEFENSE

Biomedical Laboratory, Edgewood Arsenal--conducts short-term and some long-term toxicological studies which are generally not designed to identify unknown environmental carcinogens.

HEW

National Clearinghouse for Smoking and Health--develops and disseminates data relating to smoking and health, develops information systems for such data, and conducts research on the behavorial aspects of smoking.

DEPARTMENT OF THE INTERIOR

Mining Enforcement and Safety Administration--develops and enforces health and safety standards for coal and noncoal mining operations; follows standards developed by the American Conference of Governmental Industrial Hygienists.

Bureau of Mines--conducts research on mine health and safety, including the engineering aspect of safety, primarily developing technology to implement the health standards.

Fish and Wildlife Service--conducts research concerning the safe use of chemicals to control wildlife populations and conducts a pesticide monitoring program. Enforcement powers for use or nonuse of certain chemicals are limited to Interior-held lands.

DEPARTMENT OF TRANSPORTATION

Office of Hazardous Materials--regulates the interstate shipment of hazardous materials. None of its regulations are directed specifically toward regulating hazardous materials because of their carcinogenicity.

Federal Aviation Administration--regulates aerial application of pesticides under standards set by EPA and conducts some toxicological research involving such objectives as the effects of certain chemicals on a pilot's ability to safely operate his aircraft.

INDEPENDENT AGENCIES AND ORGANIZATIONS

Energy Research and Development Administration--conducts long-term research to assess the risks associated with radiation and energy-related effluents.

National Academy of Sciences--National Research Council, Committee on Toxicology, Advisory Center on Toxicology, provides expert opinion to sponsoring agencies on toxicological problems and other related areas, such as carcinogen classification and testing. The research is conducted through literature searches and not actual experimentation.

National Science Foundation--conducts research regarding the effects of contaminants on ecosystems, participating in such programs as Research Applied to National Needs, International Biological Program, and International Decade of Ocean Exploration.

Smithsonian Institution--Registry of Tumors in Lower Animals collects, records, and disseminates information regarding tumors in lower animals but conducts no toxicological research.

World Health Organization--International Agency for Research on Cancer provides expert opinions on carcinogenesis which are published in technical reports and monographs evaluating the carcinogenic risk of chemicals to people.

NCI LIST OF KNOWN HUMAN CARCINOGENS

1. beta-naphthylamine
2. benzidine
3. 4-aminobiphenyl
4. 4-nitrobiphenyl
5. clornaphazine (bis-2-chloroethyl-2-naphthylamine)
6. mustard gas (bis chloroethyl sulphide)
7. nickel carbonyl
8. diethlystilbestrol
9. bis (chloromethyl) ether
10. vinyl chloride
11. aflatoxin
12. asbestos
13. arsenicals
14. chromates
15. estrogenic compounds
16. tobacco
17. tobacco smoke
18. soots
19. tars
20. pitches
21. asphalts
22. cutting oils
23. shale oils
24. creosote oils
25. high boiling petroleum oils
26. coke oven effluents
27. various combustion products
28. betel nut (chewing)
29. radium (note a)
30. thorotrast (note a)
31. uranium ores (radon and radon daughters)
32. other radioactive materials (note a)
33. auramine (note b)
34. magenta (note b)
35. isopropyl oil
36. wood dust (note b)

a/Carcinogenicity due to radiation.

b/Manufacturing exposure to these materials has been related to cancer induction; the materials themselves may not be carcinogenic.

The chemical substances and mixtures that have been found to cause cancer in humans are listed above. For hundreds of other substances which have been tested in the laboratory, there is evidence of carcinogenicity in rodents. In some instances the evidence is strong; in others it is barely fragmentary.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Supervisory GAO Auditor
General Accounting Office

DATE: September 17, 1975

FROM : Chemist, Office of the Associate Director for
Carcinogenesis, DCCP, NCI

SUBJECT : Classification of the Exposure Hazard Presented by Thirty-Six Chemicals and Mixtures

1. The thirty-six substances, which are on the *List of Individual Chemicals and Mixtures that Have Been Found to Cause Cancer in Man by Direct Observation of Exposed Populations*, can be separated into five categories. These classifications give some indication of the level of exposure threat which exists for the American population or some segment of the general population. The five classifications are:

Category	*Definition*
I	Controlled or restricted usage. Protection of the population requires technical surveillance.
II	Recognized as carcinogenic. Exposure is largely voluntary.
III	Implicated in human carcinogenesis by epidemiological evidence. Exposure is poorly controlled inspite of carcinogenesis hazard.
IV	Prescribed by physicians or endogenous.
V	Utilized in laboratory only.

2. The compounds and mixtures are categorized as follows:

Category I

beta-naphthylamine
benzidine
4-aminobiphenyl
4-nitrobiphenyl
nickel carbonyl
diethylstilbesterol
bis(chloromethyl)ether
vinyl chloride
aflatoxin
asbestos
arsenicals
radium
thorotrast
uranium ores (radon and radon daughters)
other radioactive materials

(count 15)

Category II

tobacco
tobacco smoke
betel nut (chewing)

(count 3)

Category III

chromates
soots
tars
pitches
asphalts
cutting oils
shale oils
creosote oils
high boiling petroleum oils
coke oven effluents
various combustion products
wood dust
auramine
magenta

(count 14)

Category IV

estrogenic compounds

(count 1)

Category V

chlornaphazine (bis-2-chloroethyl-2-naphthylamine)
mustard gas (bis-chloroethyl sulphide)

(count 2)

Isopropyl oil is no longer produced in significant quantities.

Charles R. Warner

Charles R. Warner, Ph.D.
Chemist, Office of the Associate
Director for Carcinogenesis
Division of Cancer Cause & Prevention

PRINCIPAL OFFICIALS RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Date appointed
SECRETARY OF HEW:	
David Mathews	Aug. 1975
ASSISTANT SECRETARY FOR HEALTH:	
Theodore Cooper	May 1975
SURGEON GENERAL:	
Paul S. Ehrlich (acting)	Jan. 1973
DIRECTOR, NIH:	
Donald S. Fredrickson	July 1975
DIRECTOR, NCI:	
Frank J. Rauscher, Jr.	May 1972
DIRECTOR, NIEHS:	
David P. Rall	Mar. 1971
COMMISSIONER, FDA:	
Alexander M. Schmidt	July 1973
DIRECTOR, NIOSH:	
John F. Finklea	May 1975
SECRETARY OF LABOR:	
W. J. Usery, Jr.	Feb. 1976
ASSISTANT SECRETARY FOR OCCUPATIONAL SAFETY AND HEALTH:	
Morton Corn	Nov. 1975
ADMINISTRATOR, EPA:	
Russell E. Train	Sept. 1973
CHAIRMAN, CPSC:	
Richard O. Simpson	May 1973

Chemicals and cancer

"Chemicals" and "cancer" are two words that most chemists hate to see juxtaposed. They believe, with justification, that the public at large interprets chemicals in this case as industrial chemicals only and so gets the impression that the chemical industry is responsible directly for most of the cancer problems in this country. Of course, this is far from being the case. As chemists point out constantly, everything is chemical, whether man-made or natural. Also, they stress that most cancers are related to overall environmental factors and to the way we live—for instance, to smoking and the food we eat, and not to exposure to industrial chemicals.

However, the fact remains that a few industrial chemicals have been shown to cause cancer in humans. And a growing number are suspected of doing so. Hence, the issue of the relationship between cancer and man-made chemicals is a serious and increasing one for chemical makers as well as for both the research community as it seeks ways to detect carcinogens reliably and for a host of government agencies as they strive for well-founded protocols to contain or eliminate cancer hazards.

In this special presentation, C&EN offers two views of the issue of chemicals and cancer—one from government, one from industry. They were given at different times and at different forums, hence they are not meant to rebut each other. Indeed, there is a fair amount of agreement between them. But they do represent somewhat different perceptions of what needs to be done.

Barbara Hackman Franklin has been a commissioner for the Consumer Product Safety Commission since 1973. She is serving a seven-year term. She calls for greater government involvement in the cancer issue, believing that the current efforts of government, industry, and others are "akin to 30 different acts being performed simultaneously at a three-ring circus that lacks a ringmaster." She apparently sees President Carter as filling the ringmaster role by "providing the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to size and to help reduce the confusion and uncertainty over cancer and chemicals."

John F. Schmutz is assistant general counsel for Du Pont. He calls for setting acceptable exposure levels for chemicals. For each chemical this would be the level at which it would be reasonable to predict that no one would be likely to get cancer or another chronic illness. He thinks that the legislative basis for such an approach has been set by passage of the Toxic Substances Control Act and that success now depends on the development of balanced regulations.

Commissioner Franklin is a 1962 graduate of Pennsylvania State University. In 1964 she became one of the first women to receive a master's degree from Harvard Business School. She moved to Washington, D.C., in 1971, working for two years on the White House staff where she was charged with launching a program to recruit women to fill policy-making positions in the federal government. She earlier had worked for Singer Co. and for First National City Bank in New York City.

Schmutz joined Du Pont in 1955 in the firm's Washington, D.C., law office. He assumed his present position as assistant general counsel in 1975. He graduated from Cornell University in 1955 with a chemical engineering degree. He earned a J.D. degree from Georgetown University law school in 1958.

The Franklin presentation was given last month in Los Angeles at a meeting of the Town Hall of California. Schmutz presented his views late last year at the National Symposium on Chronic Hazards.

Cancer control: a bigger role for government

Barbara Hackman Franklin, Consumer Product Safety Commission

The little-understood, thorny dilemma of chemicals and cancer may have a devastating impact on millions of people. It is a problem increasingly central to businesses. My contention is that we must find more rational, responsible ways to deal with the issues in pretty short order.

In a real-life twist to what was science fiction, some substances have surfaced as potential hazards not only to the environment but to human life as well. The rallying cry is cancer, the six-letter word that probably summons more dread and fear in the minds of the American people than any other disease. And with good reason. In the U.S., cancer is the second leading cause of death. Among all developed nations, it ranks number two. This year in the U.S. alone, some 900,000 new cases will be diagnosed.

Looking ahead, the situation may be no better. Indeed, it may worsen, because of the long incubation period of the disease and its inclination to strike middle-aged and older Americans, our fastest growing population. Expectations are that we must deal with high incidence rates for years to come, even if cures (such as those developed for many victims of Hodgkin's disease and childhood leukemia) were announced today. Eventually, according to the American Cancer Society, one in every four of us will develop cancer, and about two thirds of those who get it are likely to die.

With this as background, it is understandable why, as a nation, we must make the best possible efforts to get at the root causes and cures and to insist on better diagnosis, treatment, and rehabilitation. Three successive Presidents and Congress have recognised the importance of this work. They have boosted, for example, the budget of the National Cancer Institute, the "Pentagon" of the effort, from $180 million in 1970 to $815 million this year.

It is an expensive proposition. The program is big. But the stakes are high, too. And like so many areas of public health and safety that seem to cost a lot and rely heavily on research, controversy mounts in direct proportion to the rate at which conclusive answers and miraculous cures seem outside our grasp.

One controversy is whether the strategy aimed more at cures than at prevention is lopsided, in view of accumulating evidence

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that most cancers—perhaps as many as 60 to 90% of them—are environmental in origin. 60 to 90%? It's an astonishing figure, based on the best estimates available.

What are environmental factors? They include smoking, alcohol consumption, diet, exposure to radiation—and a range of chemicals and other substances. What does this mean? It means that more and more, the concern is over potentially dangerous substances in the air we breathe, the food we eat, the products we use and the manufacturing processes we depend upon. And, more and more, a target of the concern is chemicals.

Cranberry scare was the first of many

It was the 1959 cranberry scare that first aroused the public consciousness about environmental hazards. Others followed. Congressional hearings over passage of the new Toxic Substances Control Act sparked some of the current debate. But for most Americans, it was the proposed ban on saccharin earlier this year that brought the message home. With President Carter's recent signing of legislation to delay the ban pending the outcome of further testing, I believe we should expect even more public attention.

Developments along this line are changing the thrust of the battle against cancer. The developments are sending scientists scurrying back to their labs and lawyers back to law libraries. They are provoking Congressional hearings and regulatory proposals in the *Federal Register* at a rapid clip, and are filling the nation's newspaper columns and air waves with what cynics call the "cancer of the week" syndrome.

Across the board, chemicals and cancer are escalating into a major issue headed toward a full-blown crisis. Public confusion and the pressures on government and business "to do something" are running at about 75 decibels. Will this situation result in a government snafu? Frankly, it is too soon to tell. But it is not too early to make another prediction.

As a nation, we must come to grips with all of the issues and seek solutions that industry can live with, government can live with, and most importantly the American people can live with. If we don't, we may well have a bureaucratic snafu. But we will have far more on our hands than that. We will be courting a crisis, even a calamity whose consequences stretch far beyond the banks of the Potomac and into virtually every home, community, and workplace.

Why do I say this? Because what is at stake is the very real possibility that we stand on the threshold of reducing the ominous threat of cancer. At the same time, we face the possibility that havoc is at hand for the $100 billion a year chemical industry and for countless other industries that use chemical compounds in a variety of ways—with distinct benefits to consumers.

The hard, cold reality is that even this represents only the tip of the iceberg. Beneath the surface are technical, political, and ethical questions that are highly complex and intricate.

At our agency [Consumer Product Safety Commission], the point has been boldly underscored time and time again throughout our first four years. With a staff of 890 and a $40 million budget to deal with far more than chronic hazards, the commission already has addressed fluorocarbons, lead in paint, vinyl chloride, asbestos, acrylonitrile, benzene, and Tris.

Sleepwear problems still not resolved

It is our struggle over children's sleepwear that particularly illustrates the difficulties. Some years ago, the federal government ordered that children's sleepwear be made flame retardant to protect children from serious burn injuries. So it was, with the result that the severity of childhood burns has been reduced. But concern suddenly arose with charges that Tris, one of the chemicals that industry used to make children's sleepwear meet the federal regulations, was carcinogenic. After presentation of substantial evidence (including linking the results of long-range animal tests to human experience) and after serious economic, social, and legal considerations were weighed, the commission banned Tris last April.

Today, the debate rages on. Inside the courtrooms and outside, there are those who maintain too much was done by the government and those who complain of too little. Some object to the procedures followed. Others find fault with the substance of the ban; still others, with its implementation.

Judges still are wrestling with questions like these: In proceeding under one section of the law in order to protect consumers with a minimum of delay, did the commission violate the due process rights of producers? How far back in the distribution chain can the economic effects of the ban be spread? On Capitol Hill, companies involved in production of children's sleepwear are seeking indemnity for financial losses suffered when Tris was banned. Bills are pending in the House and Senate.

There's more.

Close on the heels of Tris came allegations that Fyrol, one of the substitutes some companies used in the wake of Tris, also might be carcinogenic. One major retailer voluntarily removed Fyrol-treated garments from the store shelves. After a public hearing, study by our staff, and review of conflicting test results, the commission determined that we lacked sufficient evidence to ban Fyrol or to require labeling. All the furor is taking its toll, and to the extent the public is perplexed or annoyed, it certainly is understandable.

The curtain has yet to come down on the safety of flame-retardant chemicals. As a result, it is neither possible nor desirable to write the final reviews. At this point, however, it is clear that the drama, if not a smash hit, is well on its way to a long-playing run. So it goes, with Tris and many, many other chemical hazards at the commission and other agencies.

In fact, federal involvement with chemicals and cancer cuts across many agencies. Eight have principal regulatory and/or research responsibility in this area, to the tune of about a billion dollars, according to my rough estimates.

President Carter has asked the Council on Environmental Quality to review the activities of the various agencies and to make recommendations how they can be done better. Our commission, the Food & Drug Administration, the Environmental Protection Agency, and the Occupational Safety & Health Administration also have agreed to take a hard look at the way we regulate chemicals and how we can work together more closely. But as Lyndon Johnson said, "The hardest part of government is not trying to do the right thing; the hardest part is knowing what the right thing is."

For all the agencies, the $64,000 question is what does constitute adequate public protection? There are other questions. Should there be consistency on the ways agencies move from research results to regulation? Or will this always boil down to a case-by-case situation within the framework of each agency's laws? How do we reduce delay in the regulatory process yet assure a solid basis for regulation, meaningful public participation, and adequate due process? And another question. Do federal agencies scrap cost/benefit thinking altogether, as some suggest?

Simply banning a substance may be the one quick way out now—but it certainly is not an adequate or acceptable answer over the long term. For example, do the benefits of saccharin for people who are diabetics outweigh the risks of cancer? And what about the substitutes for saccharin such as xylitol? Are they equally or more dangerous? Finally, what about the impacts of a ban on businesses and their employees?

My point is that banning a specific substance may indeed be the proper approach. But other factors must be weighed—before decisions are made so that we don't dreadfully shortchange the public health and safety or cause unnecessary economic upheaval.

Then there's the battle of the tests. As a nation, we're short on tests and testing protocols that are reliable, fast, and cheap. Animal tests to determine carcinogenicity can cost up to a quarter of a million dollars each and can take years. Meanwhile, the public health and safety is in limbo, government agencies really cannot do much, and industry's ability to market new, beneficial chemicals can be hamstrung.

Some short-term testing is being used but no one in or out of government is certain just yet how conclusive it is as a basis for regulation. As a result, each agency has or is formulating its own testing guidelines and criteria. So is industry. The consequences can be chaotic.

As companies try to evaluate new chemicals on the theory that safety should be tested in the lab and not in the environment, they find no uniform position—in the scientific, federal, or business communities–on what tests should be conducted and how the results should be interpreted. It can be especially bewildering if two or more agencies are focusing on the same chemical—or, as in the case of Fyrol, the same test is used but conflicting results emerge. Another issue is threshold levels of exposure—in other words, points below which carcinogenic compounds may have no adverse effects on human health.

If there were scientific certainty or even consensus on what these levels are—or even if they exist—decision making for regulators and business people would be easier. But such is not the case, and the mere suggestion of it sends many of my scientific friends up the wall. One result is that the approach of each agency differs, depending on the specific substance and the provisions of the particular law which apply.

The proposed ban on saccharin, for example, was in accordance with a specific provision of FDA's law, the Delaney clause, which triggers an automatic ban. The laws administered by the Consumer Product Safety Commission, on the other hand, do not contain a Delaney-type provision. At our agency, regulation must follow a decision of a majority of the commissioners that a substance presents an "unreasonable risk" of injury, illness, or death.

Effective course of action needed

Where do we go from here? I only wish I could plot an effective course of action which would make sense for industry, government, and most of all, for consumers—those who must feel increasingly confused or cynical. And frankly, I'm hard pressed to blame them.

At the moment, products whose benefits consumers have enjoyed, sometimes for years, are headlined as hazards that may be garrotes around their throats. At the same time, they are besieged with conflicting news reports that there is absolutely no cause for concern. Is nothing safe any more, they ask? Are we victims of overdramatization by the media? Regulatory overkill or underkill? Industrial conspiracies? Is this the necessary price we pay for living in a highly industrialized society?

I say to you emphatically that neither I nor any other single individual, agency, company or public interest group has conclusive answers to all of these questions. The issues are much too complex and interdependent and their impact too extensive to expect that the answers are the sole prerogative of any one person, organization, or profession. But the questions are good ones, and they underscore the urgency and seriousness of the challenge of chemicals and cancer before us all. Fundamentally, this strikes at the heart of my major concern.

It is that we in government seem to be talking too much to ourselves and too little with industry and consumers, whose knowledge and concerns may differ—or may be the same. The point is that we're not sure. Industry, too, is cruising along on its own course—without full consideration of the attitudes and information of others. It's akin to 30 different acts being performed simultaneously at a three-ring circus which lacks a ringmaster.

Eventually—or sooner I hope—we all must recognize that the heady problems with chemicals and cancer are truly shared ones and that it serves the broad public interest to face them squarely. So it goes with the solutions, if they are to be sound, equitable, and lasting. They, too, must reflect information and involvement from many sources and in the final analysis, consensus and compromise—abhorrent though these words may seem to some.

This is why, in many public forums, I have called for wide, open, and frank discussion of the causes and control of cancer. It is essential that all segments of the public be more adequately informed and actively concerned and involved. Not just when cancer strikes a family member or friend. Not just in reaction to a specific regulatory proposal. And not just when writing a check to support cancer research and related activities, as important as all of these are.

President Carter must spearhead effort

The concern must go much deeper, and the public consciousness and understanding must be raised proportionately.

This is why I repeatedly urged President Carter to provide the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to size and to help reduce the confusion and uncertainty over cancer and chemicals. With vigorous support from the White House, I believe we can achieve it—and head off the possibility of a government snafu.

The first major step needed was the one the President took—to ask an interagency group to conduct a study and make recommendations. But much more must be done. The next step urgently needed is serious discussion with the scientific, academic, and medical communities; business community; the public and the federal agencies themselves—beginning now. Together, we must explore the issues and suggest sound strategies to deal with them.

This is why I will continue to urge formulation of a national policy on carcinogens with the weight of the White House behind it.

Again, government must take the lead responsibility but the policy must reflect the diverse concerns of the public. A policy, developed in concert with the public, should articulate—so that everybody will know—the posture and program of the federal government in this area and the guiding principles behind it.

At a minimum, I believe a policy must address issues including these: information needed to regulate cancer-causing chemicals, the tests that should be used, how the results should be interpreted, and factors other than public health that should be taken into account.

The policy must recognize the need for flexibility so that developing scientific knowledge can be applied and so that the individual agencies can perform the jobs that the President and Congress expect. Perhaps most of all, such a policy must spell out the magnitude of the problem, the need for adequate consumer protection and for timely, intelligent, and informed action to achieve it. I am, in essence, urging support for *more* governmental involvement.

Historically, business has resisted the concept of government intrusion—and not without sound reason. But with chemicals and cancer, this is not the response called for. With this issue and the chaos and high stakes that surround it, more federal involvement is inevitable and should be welcomed, if it is rational and responsive.

For business, the immediate challenge—and I believe, the opportunity—is to make a serious commitment to working with government. We need actions that serve the public interest and are good business—before the chaos runs its course and before decisions are made when there are no longer good alternatives.

Is there room for voluntary initiatives? Of course. Government regulation is never the complete answer. That was the name of the game when Congress passed the Consumer Product Safety Act and created our agency and even more recently, when EPA's Toxic Substances Control Act was enacted. The spirit of both, as I see it, is that it is in the public interest and industry's own economic self-interest to take any precautionary steps needed before products are marketed, not afterwards.

With certain chemical hazards, however, the crux of the issue is precisely what these "precautionary steps" are. This is why, at this point, more governmental leadership is needed. Serious discussions—triggered by the highest level of our government—could bring perspective, direction, and visibility to the need to control cancer. A national policy would establish the framework, lay the ground rules, and coalesce the diverse concerns of many federal agencies, industry, and the public.

Not all the scientific evidence to confirm or refute our worst fears is in. But it seems to me that we know enough to know the odds are against complacency or reluctance to work together.

Can we reduce the uncertainty and broad array of issues to a common denominator from which total unanimity will emerge? Maybe not. The risks are such that we must try. □

Chronic health hazards: a national challenge

John F. Schmutz, Du Pont

Chronic health hazards are of concern to me, my company, industry, and the nation. Twenty-five years ago, two or three chemicals were known to cause cancer in man. Today, the Occupational Safety & Health Administration regulates 17 as potential carcinogens, and the National Institute for Occupational Safety & Health has a list of 2415 suspected materials. We must move up aggressively to deal with the issue—and we are.

We are now in the same status with regard to chronic hazards as we were with respect to air and water pollution control five to 10 years ago. Key laws have been enacted, and we are in the process of developing policies and the bases for regulations necessary to carry out the statutory authority. From a policy viewpoint, I feel we can draw from our prior experiences with the environment in charting a course which focuses our effort, conserves our resources, and makes positive progress toward a clean and healthful environment.

Today, I would like to:

- Provide a perspective to chronic health hazards.
- Discuss the critical issues, particularly acceptable risk.
- Provide a suggestion as to how we might deal with those issues.

Because it is so personal to each of us, the question of chronic illness, particularly cancer, is one that is difficult to view in perspective. The deep concern for those stricken leads us to react emotionally rather than rationally. To manage chronic health hazards effectively, they must be looked at by a reasoned approach, based on available facts. Let me give you a list of five which help me frame the chronic health hazards issue with respect to chemicals.

First, chemicals are not necessarily "good" or "bad," "man-made" or not. Almost everything in nature involves chemicals. To change from man-made materials to naturally based products does not avoid chemicals. Food is as much an organic chemical as a plastic sheet or a solvent.

Second, chemical carcinogens and other chemical chronic health hazards are not necessarily man-made. Asbestos, which helped initiate the focus on chronic health hazards, is a chemical and a naturally occurring carcinogen. Peanuts and grains frequently contain traces of aflatoxin, a potent carcinogen formed by a common mold. Charcoal-broiled steaks contain benzopyrene, a carcinogen.

Third, many chemicals essential for health in small quantities are highly toxic in larger quantities. We would die without zinc, manganese, copper, molybdenum, selenium, chromium, fluorine, silicon, nickel, tin, vanadium, potassium, and many others that also have severe acute and chronic toxicity in larger amounts. For example, nickel and selenium in some forms are carcinogens.

Fourth, the incidence of cancer is not rapidly increasing. If the effects of cigarette smoking are excluded and statistics are age adjusted, cancer incidence and cancer deaths per unit of population have remained about constant over the past 25 years.

Fifth, the statement that 80 to 90% of cancers are environmentally caused does not mean that 80 to 90% of cancers are caused by industry. Environment in this sense includes not only the air we breathe and water we drink, but our diet and all elements of our life style, at home and elsewhere, on and off the job. "Environment" does not equal industry. The major causes of environmental cancer are smoking and diet. Reliable experts estimate that 5% or less of cancer is industrially related. That number includes known hazards such as asbestos, β-naphthylamine, and others now well under control.

Industrial chemicals part of problem

In summary, health hazards are a national problem resulting from a variety of causes of which industrial chemicals are only a part. Let me hasten to add that because of the human suffering involved, industrial chronic health hazards are a major concern to industry. However, industrial hazards are far from being the principal cause of chronic illnesses.

Why then the focus on industry? This brings me to my second topic—the need to define the issues. Cancer is an immediate, readily identifiable, and emotional issue in all our lives. All of us have had relatives who have died from it. Also, tragic events in the past several years have focused on several instances where cancer or other serious chronic illnesses have been caused by industry-related chemicals. This has led to a tendency to assume that if an industrial chemical is present in the environment, it is harmful. Emotionally, we are prone to consider a man-made chemical found in the environment as more serious

than a naturally occurring chemical found there in the same or larger quantities.

Enormous strides in the detection of chemicals in our environment also have helped focus attention on the many chemicals to which workers have been exposed over long periods. During the past five years, our techniques for detecting chemicals have increased greatly. In water, for example, accuracy of detection has progressed from parts per million to parts per billion—from drops per 100 gal to drops per *100 thousand* gal.

The rapid evolution in toxicology and epidemiology in pinpointing hazards over the past 20 years also has made it difficult to segregate the events of today from the events of many years ago. Cancer and other chronic illnesses diagnosed today often have resulted from exposure of many years ago when hazards were unknown and practices were far different.

Judging the work practices of 20 years ago by the increased knowledge and more informed standards of today often is not constructive. Let me note one of Du Pont's experiences in this regard.

More than 20 years ago, Du Pont established a system to collect morbidity and mortality data. Its purpose was to provide one check among many on the exposure of our workers to chronic health hazards. In the past several years, the cancer registry part of this epidemiology program has been examined in depth by government. It was one of the few available to examine. In voluntarily submitting data from it, we ourselves have pointed out deficiencies in our registry—deficiencies not unique to our system. Yet, focus from some sources on shortcomings has unfortunately masked the fact that it is a unique and pioneering effort and a contribution to the health of our employees. There is an emotional conditioning to focus on the negative, rather than the positive.

I think there also is some element of frustration caused by the very nature of chronic hazards. In most things, we are able to see improvement in response to our positive actions. Fish are returning to the water. People can swim again in waters previously polluted. There is reduced smog and air pollution. But with chronic hazards exposures of many years ago may cause illnesses today and possibly will for years to come. The results of today's control are not yet apparent.

That frustration increases the pressure to "do something" and feeds the desire to mandate uniform technology-forcing control at "absolutely" safe levels. I submit, however, that *that* approach will not solve the problem of chronic hazards nor is it in the national interest.

Because of the foregoing, there is a critical need to attempt to bring objectivity to the issue of chronic health hazards and to focus upon what I believe to be the critical issue, an acceptable level of risk.

Zero risk or zero exposure is neither technically possible, nor, given its consequences, desirable. For example, it would not be possible to reduce the exposure to a gaseous chemical to zero in a plant or in products made from that material. Industrial exposure could be reduced to a level above zero at which cancer would not be expected. There may be no hazard from minute quantities of residual monomer in a polymer, but, technically, the quantity of monomer could not be zero.

The delicious aroma of your Thanksgiving turkey is in part caused by acrolein, a highly toxic chemical. That delectable picnic-grilled meat contains benzopyrene, a carcinogen. Are we going to stop all turkeys for Thanksgiving or outdoor grills? Are we going to ban peanuts? Those would be the consequences of zero risk.

In speaking of an acceptable risk, I am not talking about those situations in which it is known that the level and duration of exposure would be likely to cause some people to contract a chronic illness. What I am talking about is accepting a level of risk at which it is unlikely that anyone will become chronically ill but at which one *cannot* prove whether *or not* there is 100% safety. It means living with reasonable assurance of safety and acceptable uncertainty.

Congress has accepted that uncertainty. The House report of the Toxic Substances Control Act states: "The committee has limited the administrator to taking action only on unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the committee does not make."

Note that many years ago the concept of acceptable risk was adopted in handling radiation. The risk of x-rays is generally accepted. The nuclear power industry is regulated on that premise.

The concepts of zero exposure and zero risk ignore another point—the many positive benefits of chemical products. They ignore the fact that those products have become essential to our health and safety as well as our comfort and convenience. They ignore the many jobs made possible by chemicals. They ignore the many socially beneficial results obtained with taxes generated by the manufacture of products made from them.

Acceptable levels of risk must be set

How is an acceptable level of risk set? I would start with the fact that the effect of carcinogens and other chronic health hazards is related to dose and period of exposure. Considering level and duration of exposure, those conditions should be found under which no effect is observed. Then a substantial margin of safety should be applied by further reducing the level and duration of exposure. Let me add, however, that a necessary element of this approach is full disclosure of all known significant hazards to all those accepting the risk.

It follows from the concept of acceptable risk, that use of a rigid guideline of control to the lowest level feasible is inappropriate, except as an interim measure. With a potent carcinogen, for which a no-effect level has not been established, lowest level feasible may present an unacceptable risk if it is continued over a prolonged period. In such case, use of the carcinogen should be discontinued if a no-effect level cannot be established. In other cases, control to the lowest level feasible may unnecessarily waste jobs as well as capital, energy, and other resources.

Duration of exposure, as well as level, is important. Control to a level while further data are gathered may provide reasonable assurance of safety and acceptable uncertainty. Prolonged exposure at that level may be unacceptable.

I can well sympathize with the regulators' frustration at extended proceedings and the delay involved in a product-by-product approach. I agree that factors such as oncogenicity vs. carcinogenicity and screening tests are subject to policy decisions. I agree with many aspects of recent proposals for regulation of chronic hazards in the workplace. But, ultimately, hazards must be evaluated on a product-by-product basis. Furthermore, controls mandated—that is, whether administrative controls, engineering controls, or personal protective equipment are to be used—should vary from case to case. In water pollution, the promulgation of effluent guidelines has confirmed the administrative feasibility of the case-by-case approach. The National Permit Discharge Elimination System permits to tens of thousands of individual plants confirm it.

Just as product-by-product evaluation of risk is essential if there is to be socially effective regulation, so, too, is the setting of priorities for efforts. The nation does not have the laboratories or the toxicologists to test the chronic effects of all chemicals immediately, nor would such effort be desirable. I endorse the efforts of the advisory committee, established under the Toxic Substances Control Act to help set priorities. Selectivity also should be applied to all aspects of the regulation of chronic hazards. For example, broad production of detailed data can only obscure the critical issues and delay meaningful analysis by the government.

Let me describe a case history to illustrate the complexity of the carcinogen issue from an industrial viewpoint. One of our promising new products, Kevlar aramid fiber, is made using hexamethyl phosphoramide (HMPA) as a polymer solvent in an early step. That chemical is and has been used widely as a solvent in laboratories for many years. No human cancer has been attributed to it.

From our earliest use, because of acute hazards, we had treated HMPA as a no-contact chemical and controlled it to very low levels. Based on early toxicological screens, rat inhalation tests also were begun, but before we could run the tests, we had to develop special techniques to handle the low exposure levels. Then, eight months into the rat tests, cancer emerged at levels as low as 400 ppb and after 13 months, at 50 ppb.

Although our cancer registry showed no evidence of cancer-related problems with employees, one first step was to quickly and systematically disclose our finding to employees and government agencies to which our findings would be helpful. Since the chemical was widely used in research, we also sought disclosure in major publications.

Concurrently, as the test data developed, we lowered the permissible airborne exposure limit to 25 ppb then to 5 and, within one year, to 0.5 ppb. Initially, we had no method to detect such small quantities, the equivalent of about one drop per 10 million gal. Therefore, our research and engineering people had to devise a test method. In the plant, a combination of engineering controls and personal protection was used, the latter because of the freedom of manipulation required of employees for some of the fiber operations.

Simultaneously, new animal tests were initiated to substantiate a no-effect level.

Although the search for an alternate was begun immediately, at least 100 man-years of research will be necessary to re-engineer the process even after a suitable candidate is found.

I have attempted to give you a perspective on chronic hazards from an industry viewpoint and an example of how one company has dealt with one new discovery. How should such hazards be regulated?

Basis for sound regulation has been provided

The condition precedent to sound regulation is an adequate and balanced legislative base. With the passage of the Toxic Substances Control Act, which was generally supported by industry, that base has been provided. We can all thank Congressman [Bob] Eckhardt for his efforts that made that legislation possible. Now success of its implementation will depend critically on balanced regulation.

An Interagency Regulatory Liaison Group, representing the Consumer Product Safety Commission, the Environmental Protection Agency, the Food & Drug Administration, and OSHA, has been formed to coordinate approaches to such issues as testing, risk assessment, regulation, and enforcement. Another group called the Toxic Substances Control Act Group, chaired by J. R. Speth, has been formed to develop policies and coordinate the federal regulatory approach to toxic chemicals. I believe that these groups can do much to help keep that regulation within the bounds of Congressional intent by assuring a stable, coordinated approach. I support and encourage them in their work.

To the regulators, I suggest five guidelines in drafting chronic hazards regulations.

First, I suggest a review of data within federal agencies to determine where additional data acquisition or development may be necessary. Where gaps exist, EPA can selectively require submission of information from the private sector and develop testing requirements. Appropriate selection criteria would include the magnitude and routes of exposure, the extent of existing data, and chemical properties. This approach would focus on those chemicals that may present unreasonable risks and permit meaningful utilization of existing testing resources to evaluate priority needs.

Demands for reporting of substantial data on all chemicals as currently proposed by EPA for TSCA inventory reporting would be counterproductive and serve merely to slow down review of major high-risk areas of concern. Similarly, recommendations for testing by categories of chemical substances threaten priority needs by requiring extensive and unnecessary pre-emption of limited testing resources.

Second, there should be full disclosure of all significant hazards to all those who may need to act on that information, including employees, customers, the government, and others. Existing authority under TSCA provides an adequate statutory basis to require industry to notify the government of pertinent health and safety data.

Third, workplace concentrations of suspected animal or human carcinogens should be promptly but temporarily limited to the lowest feasible level considering length of exposure, the physical form of the material, its concentration, and existing toxicological data. The level of control should take into consideration existing data and apply a safety factor. For example, in some cases the acceptable airborne concentration might be one tenth of the observed no-effect concentration in a suitable animal study.

The level and duration of control, not the means thereof, should be of primary concern. The means of control should be a practical combination of engineering controls to the extent technically and economically feasible augmented by administrative controls and personal protective equipment as necessary.

Fourth, an acceptable risk level should be defined as quickly as possible. Acceptable risk should be based on a suitable reduction from the observed no-effect level in animals, epidemiology studies, or their equivalent. Functionally, the acceptable risk level would be a level at which it would be reasonable to predict that *no one* would be likely to get cancer or another chronic illness from the chemical. In making this determination, it must be recognized that one could not prove, nor is it possible to ever prove, that some uniquely sensitive person could not get cancer.

Fifth and finally, there should be control to the acceptable exposure level. If extended testing is required to determine that level, we should continue control to the lowest level feasible. If an acceptable risk level cannot be determined and the product cannot be made and used safely, then the operation should be discontinued.

It will be a challenge for industry, labor, the government, and the public to work together objectively on chronic hazards. But the stakes are high and we must do it. Our mistakes and successes will not be measured for many years. In the interim—while we are hard at work finding and reducing the hazards—good judgment, objectivity, and an acceptance of the fact that life cannot be made risk-free must tide us over. □

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Bick, Thomas, and Roger E. Kasperson. Pitfalls of hazard management: the CPSC experiment. Environment, v. 20, Oct. 1978: 30-42.

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Clark, Timothy B. New approaches to regulatory reform--letting the market do the job. National journal, v. 11, Aug. 11, 1979: 1316-1322.
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Feldman, Laurence P. The Consumer Product Safety Commission: benefit or boondoggle? Journal of consumer affairs, v. 11, winter 1977: 25-42.
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Hutt, Peter Barton. Balanced government regulation of consumer products. Food drug cosmetic law journal, v. 31, Nov. 1976: 592-604.
"This paper . . . deal[s] broadly with the question of how government regulation of consumer products can be controlled to prevent either indifference to genuine problems or unnecessary overregulation. It . . . briefly examine[s] the rationale for and mechanisms of government regulation and review[s] possible ways of achieving control of agencies in order to assure balanced regulatory activities."

The impact of Federal regulation. Challenge, v. 19, Nov.-Dec. 1976: 34-52.
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Kytle, Rayford P., Jr. New dimensions for quality and product safety. Atlanta economic review, v. 26, May-June 1976: 24-27.
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Levy, Robert, and Mark Levenson. A record year for recalls. Dun's review, v. 113, Jan. 1979: 28, 30-34.

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Lowrance, William W. Of acceptable risk: science and the determination of safety. Los Altos, Calif., William Kaufmann [1977] 180 p.

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Soman, Shirley Camper. Let's stop destroying our children. New York, Hawthorn Books, 1974. 274 p. HQ792.U5S65 614.8

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Advertising, management, and society; a business point of view. Francesco M. Nicosia, ed. New York, McGraw-Hill, 1974. 386 p. HF5813.U6N52 659.10973

Brengle, John E. Access of the poor to basic economic needs: a new concern in freedom of speech decisions. Indiana law journal, v. 54, fall 1978: 83-94.

"The Supreme Court has recently expanded the right of consumers to receive relevant product information by ruling that 'commercial speech,' information that concerns only financial transactions, is protected by the first amendment." Comment examines the ways in which the Court's concern for the poor's access to basic needs has been evidenced in the professional advertising cases and how it may affect future decisions.

Butters, Gerard R. A survey of advertising and market structure. American economic review, v. 66, May 1976: 392-397.

Discusses the relationship between advertising, concentration, and profitability. Also examines the role of advertising in informing consumers about the existence of individual producers and the prices of their products.

Can't get enough of that sugar crisp: the First Amendment right to advertise to children. New York Universtiy law review, v. 54, June 1979: 561-599.

Comment "examines the proposed ban on children's advertising in light of recent developments in the constitutional doctrine of commercial free speech. It concludes that the proposed regulations are overly broad and, therefore, unconstitutional."

Conklin, John E. "Illegal but not criminal." Englewood Cliffs, N.J., Prentice-Hall [1977] 153 p.

Examines "the naive and dangerous attitudes that permit consumer fraud, false advertising, and a host of other 'clean crimes,' from tax, stock, and securities fraud to embezzlement and bribery."

Culkin, John. Selling to children: fair play in TV commercials. Hastings Center report, v. 8, June 1978: 7-9.

Focuses on the debate between advertisers and public-interest groups on the issue of TV advertising aimed at children. Argues that "the battle is so unequal that federal regulatory agencies have a responsibility to act on behalf of the interests of children and parents."

Demkovich, Linda E. Pulling the sweet tooth of children's TV advertising. National journal, v. 10, Jan. 7, 1978: 24-26.

"The Federal Trade Commission is trying to decide how much protection children need from the advertisements they see on television. Critics say the ads for sugary cereals and other products shouldn't be shown to children, but the industry says the critics are off base. The FTC may decide this month what it will do about the complaints."

Fairness and unfairness in television product advertising. Michigan law review, v. 76, Jan. 1978: 498-550.

Article sketches some findings on the impact of television advertising; examines how the FCC (via the fairness doctrine) and the FTC (via deceptive advertising regulation) "could provide for the effective presentation of contrasting points of view on controversial issues implicitly or explicitly raised by television product advertising, could ensure that the implicit messages of such advertisements are delivered fairly and without deception, and could counter the adverse effects of such advertising;" and considers constitutional limits on regulatory action.

Farber, Daniel A. Commercial speech and First Amendment theory. Northwestern University law review, v. 74, Oct. 1979: 372-408.

Article proposes a bifurcated approach to commercial speech cases: a relatively lenient test (the O'Brien test) should be used for State regulation based on the contractual nature of the speech (e.g. misrepresentation). But in other cases, as where State regulation restricts the flow of information, the general First Amendment speech tests should apply.

Fohr, Bruce. War: FTC vs. advertisers. Columbia, School of Journalism, University of Missouri, 1976. 6 p. (Missouri. University. Freedom of Information Center. Report no. 355)

"The antagonism between the advertising industry and the Federal Trade Commission is increasing as members of the industry are balking at the commission's latest regulation 'tactics.' Advertisers call it over-regulation and say the situation has reached the point of warfare."

Kramer, Albert H., and Wesley J. Liebeler. Marconian problems, Gutenbergian remedies: evaluating the multiple-sensory experience ad on the double-spaced, typewritten page. Federal communications law journal, v. 30, winter 1977: 35-46.

Authors debate the extent to which advertising should be regulated. Kramer contends that not only the words but also the "sensory experience" projected by ads should be examined for misleading impressions. Liebeler agrees that deceptiveness should be eliminated, but feels that much of Kramer's argument is based on disapproval of consumer spending decisions rather than on deceptive ads.

Legal advertising ushers in a new era for the bar. New England business, v. 1, Feb. 1, 1979: 17-19.

Focusing on the New England area, considers the impact of the recent Supreme Court decision which "struck down rules banning advertising by lawyers." Discusses deliberations by the Massachusetts Supreme Judicial Court on "whether electronic media-radio and television-advertising will be permitted."

Luebke, Barbara F. The commercial speech doctrine. Columbia, School of Journalism, University of Missouri, 1977. 6 p. (Missouri. University. Freedom of Information Center. Report no. 372)

"The author reports on the legal status of commercial speech, from the Supreme Court's 1942 ruling in the Chrestensen case, to the 1975 Bigelow decision. The report indicates confusion and inconsistency in the courts, marked by rulings which have ranged from acknowledging no constitutional protection, to those according full First Amendment protection."

McChesney, Fred S., and Timothy J. Muris. The effect of advertising on the quality of legal services. American Bar Association journal, v. 65, Oct. 1979: 1503-1506.

Argues that "when lawyer advertising leads to lower prices, it need not result in a loss of quality. In fact, quality may be enhanced."

McKie, James W. Advertising and social responsibility. Society, v. 16, Mar.-Apr. 1979: 39-43.

Sketches the controversies concerning the effect of advertising on consumer preferences and whether advertising confers monopoly power on the seller. Doubts the value of government regulation of advertising, since "everything that makes a 'socially optimum' advertising policy difficult for the responsible firm would also create difficulties for government regulation."

Metzger, Michael B., and Barry S. Roberts. The new commercial speech doctrine. MSU business topics, v. 27, spring 1979: 17-23.

Examines legal cases regarding advertising and finds "the advent of commercial speech doctrine extending the protection of the First Amendment's freedom of speech to previously unprotected advertising language."

Mongoven, James F. Advertising as a barrier to entry: structure and performance in the soft-drink industry. Antitrust law & economic review, v. 8, no. 1, 1976: 93-101.

Says that for the soft-drink industry "concentration is now high, entry into the national market has stopped completely, and consumer prices for soft drinks are substantially above the competitive level. Large-scale advertising has once more taken its toll, converting what might have been a highly competitive American industry into a tightly oligopolistic one that serves the public poorly."

Pitofsky, Robert. Beyond Nader: consumer protection and the regulation of advertising. Harvard law review, v. 90, Feb. 1977: 661-701.

Article "examines the economic and legal justifications for ad regulation, suggests the contours of a consumer-oriented regulatory program, and assesses recent departures from traditional ad regulation by the Federal Trade Commission."

Roberts, Barry S. Toward a general theory of commercial speech and the First Amendment. Ohio State law journal, v. 40, no. 1, 1979: 115-152.

Article surveys recent Supreme Court decisions which "have eliminated the doctrine that commercial speech is wholly outside the protection of the first amendment (in other words, that it is really 'nonspeech'), and in its place have established the principle that speech that does no more than propose a commercial transaction is entitled to a 'lesser degree' of constitutional problem. . . . Although this modified doctrine is well-suited to commercial speech, its appropriateness for other areas is highly questionable."

Skitol, Robert A. The defense of a false advertising case. Food drug cosmetic law journal, v. 33, Feb. 1978: 48-58.

Article discusses the Federal Trade Commission's requriement of a "reasonable basis" of substantiation for claims made in advertisements. Critiques the case-by-case approach of the Commission and concludes that "it is hard to devise an effective advertisement immune from some risk of an FTC 'reasonable basis' complaint; it is hard to mount an effective defense when such a complaint is issued; and it is hard to negotiate a settlement."

Swagler, Roger M. Consumers and the market; an introductory analysis. 2d ed. Lexington, Mass., D. C. Heath, 1979. 336 p.
HC110.C63594 1979 381.3

Thompson, Mayo J. Government regulation of advertising: killing the consumer in order to "save" him. Antitrust law & economics review, v. 8, no. 1, 1976: 81-92.

Maintains that the regulation of advertising is not in fact designed to maximize the economic well-being of consumers.

Trauth, Denise M., and John L. Huffman. New U.S. Supreme Court philosophy on advertising faces opposition. Journalism quarterly, v. 56, autumn 1979: 540-545.

Contend that the "court ruling in two cases that commercial advertising has First Amendment protection is in conflict with actions of agencies on behalf of consumers."

U.S. Congress. House. Committee on Government Operations. Federal Trade Commission oversight--rulemaking, advertising, and consumer access; fourth report together with additional views. Washington, U.S. Govt. Print. Off., 1977. 107 p. (95th Cong., 1st sess. House. Report no. 95-472)

U.S. Congress. Senate. Committee on Commerce, Science, and Transportation. Subcommittee for Consumers. Oversight of the Federal Trade Commission. Hearings, 96th Cong., 1st sess. Washington, U.S. Govt. Print. Off., 1979. 808 p.

"Serial no. 96-69"
Hearings held Sept. 18-Oct. 10, 1979.

Wright, John Sherman, and John E. Mertes, compilers. Advertising's role in society. St. Paul, West Pub. Co., 1974. 501 p.
HF5821.W74 659.1

D. DEBATE PROPOSITION THREE--RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR TESTING AND MARKETING ALL PRODUCTS WITH POTENTIALLY CARCINOGENIC EFFECTS ON HUMANS

Agran, Larry. The cancer connection; and what we can do about it. Boston, Houghton Mifflin, 1977. 220 p. RC268.A37 616.99405

Allera, Edward J. An overview of how the FDA regulates carcinogens under the Federal Food, Drug, and Cosmetic Act. Food drug cosmetic law journal, v. 33, Feb. 1978: 59-77.

Gives background on the Delaney Clauses in the Federal Food, Drug, and Cosmetic Act, which require the FDA to test specifically for carcinogens. Discusses other criteria and procedures that the FDA uses to regulate carcinogens in food, drugs, and cosmetics.

Armstrong, June. Pick your poison: a dictionary of food additives. 2d ed. North Hollywood, Calif., Model Print, 1974 [c1973] 117 p.
TX553.A3A75 664.0603

Blum, Arlene, and Bruce N. Ames. Flame-retardant additives as possible cancer hazards. Science, v. 195, Jan. 7, 1977: 17-23.

"The main flame retardant in children's pajamas is a mutagen and should not be used."

Carter, Luther J. How to assess cancer risks. Science, v. 204, May 25, 1979: 811-816.

"Federal agencies are divided on quantification; OSTP [Office of Science and Technology Policy] proposes a centralization of authority."

Clark, Timothy B. At last, a battle plan for the regulatory war on cancer. National journal, v. 11, Oct. 27, 1979: 1808-1811.

"After years of interagency rivalries, five federal agencies have negotiated a battle plan for the war on cancer that is aimed at eliminating inconsistencies in the way the government regulates cancer-causing substances in the environment, the workplace and the market. The five-agency agreement also paves the way for a period of rapid growth in such regulation."

Corbett, Thomas H. Cancer and chemicals. Chicago, Nelson-Hall, c1977. 210 p.
RC268.6.C67 616.994071

Demkovich, Linda E. The food safety laws--can risk-benefit tests work? National journal, v. 11, Mar. 31, 1979: 516-519.

"Should potentially hazardous food additives be permitted on the market if they provide other kinds of health benefits? Should economic considerations enter into decisions to order additives off the market? These are some of the questions that the Food and Drug Administration and Congress are asking as they review the nation's food laws."

Doll, Richard, Sir. Strategy for detection of cancer hazards to man. Nature, v. 265, Feb. 17, 1977: 589-596.

"It is now clear . . . that most, if not all cancers have environmental causes and can in principle be prevented. The identification of environmental hazards and clarification of the mechanisms through which they cause disease are thus among the highest priorities in cancer research."

Epstein, Samuel S. The politics of cancer. Rev. and expanded ed. Garden City, N.Y., Anchor Press, 1979. 628 p. RC268.E67 1979 362.19699400973

Franklin, Barbara Hackman, and John F. Schmutz. Chemicals and cancer. Chemical & engineering news, v. 56, Jan. 16, 1978: 34-39.

Presents two views of the relationship between cancer and chemicals; one from a member of the Consumer Product Safety Commission and the other from an executive of Du Pont Corporation.

Harkins, Robert W. Food additive safety evaluation. Food drug cosmetic law journal, v. 32, Apr. 1977: 182-193.

"When setting priorities for safety evaluation of food ingredients, two broad overlapping areas of concern must be recognized: (1) the total universe of chemicals in man's environment of which food ingredients are a small and relatively well-defined segment, and (2) the relative potential hazard of the individual food ingredients."

Henteleff, Thomas O. The Delaney myths. Food drug cosmetic law journal, v. 33, Aug. 1978: 396-404.
Describes popular misconceptions concerning the provisions of the Delaney clause of the Federal Food, Drug, and Cosmetic Act. The clause bans the use of carcinogenic food additives, within the act's definition of that term.

Hines, William, and Judith Randal. Behind the saccharin uproar. Progressive, v. 41, June 1977: 13-17.
Argues the case in support of the action taken by the FDA to ban saccharin from American food supply.

Hutt, Peter Barton. Unresolved issues in the conflict between individual freedom and government control of food safety. Food drug cosmetic law journal, v. 33, Oct. 1978: 558-589.
Contends that our current no-risk food safety policy is unattainable because carcinogens pervade our entire food supply. Concludes that Congress and the FDA must begin to formulate new food safety policy and outlines related legal considerations. Discusses sources of food safety data and the need for consistent rules to guide regulatory decisions. Urges the participation of qualified scientists and the general public in food policy formulation.

Kirschten, Dick. The new war on cancer--Carter team seeks causes, not cures. National journal, v. 9, Aug. 6, 1977: 1220-1225.
Describes the Carter Administration's efforts to coordinate the activities of agencies regulating toxic substances. The backgrounds of Carter appointees to enforcement and research positions are outlined.

Lijinsky, William. How nitrosamines cause cancer. New scientist, v. 73, Jan. 27, 1977: 216-217.
"By systematically modifying the molecular structure of nitrosamines it is proving possible to pin down chemically the cancer-inducing activity of these important environmental contaminants."

Maugh, Thomas H., II. Chemical carcinogens: how dangerous are low doses? Science, v. 202, Oct. 6, 1978: 37-41.
Discusses the controversy over attempts to determine if, and at what levels of concentration, certain chemicals become carcinogenic.

O'Connor, Charles A., and Stephen C. Woodward. Filling gaps in chemical carcinogenesis: a defensive research program. Chemical times & trends, v. 3, Oct. 1979: 10-13, 48-53.
"To date federal agencies have regulated the majority of suspect chemical carcinogens based not upon human but upon animal data. Avoiding human exposure to carcinogens by identifying them first in experimental animals, of course, is the ideal. Yet it assumes what is still at issue, namely, whether experimental data is a reliable predictor of human carcinogenicity."

Oser, Bernard L. Are food additives overregulated? Food drug cosmetic law journal, v. 31, Nov. 1976: 627-635.

Describes "the plethora of regulations applicable to food safety and the relative roles of the FDA and Congress."

Regulatory aspects of carcinogenesis and food additives: the Delaney case. Frederick Coulston, ed. San Francisco, Academic Press, 1979. 397 p. (Ecotoxicology and environmental quality, 2d v.)

RC268.65.R44 616.994071

Rhein, Reginald W., Jr., and Larry Marion. The saccharin controversy: a guide for consumers. New York, Monarch Press, c1977. 122 p.

RC268.7.S23R46 616.994-71

Rorvik, David M. Cancer and cancer research. New York, Alicia Patterson Foundation, 1977. 28 p.

Article discusses the politics of cancer research, including the problems Linus Pauling has had with the National Cancer Institute over the use of vitamin C in cancer research.

Scott, Rachel. The political hazards of cancer research. Environmental action, v. 8, June 4, 1977: 10-13.

Presents a critical look at American cancer research, especially as it applies to environmental and occupational health.

Staats, Elmer B. Federal policies for regulating carcinogenic compounds. GAO review, v. 11, winter 1977: 1-9.

The Comptroller General comments on the "GAO's work in reviewing Federal policies for regulating cancer causing chemicals in our environment," and reviews the tobacco-smoking controversy.

U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Health and the Environment. Proposed saccharin ban--oversight. Hearings, 95th Cong., 1st sess. Mar. 21 and 22, 1977. Washington, U.S. Govt. Print. Off., 1977. 592 p.

"Serial no. 95-8"

U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Oversight and Investigations. Cancer-causing chemicals--part 2, chemical contamination of food. Hearings, 95th Cong., 2d sess. Feb. 14, 16, and 24, 1978. Washington, U.S. Govt. Print. Off., 1978. 313 p.

"Serial no. 95-118"

U.S. Congress. Office of Technology Assessment. Cancer testing technology and saccharin. [Washington, for sale by the Supt. of Docs., U.S. Govt. Print. Off.] 1977. 149 p.

Report concludes that saccharin is a carcinogen, based on the evidence of "a significant increase in the incidence of bladder cancer in rats" fed high levels of saccharin, which "leads to the conclusion that saccharin is a potential cause of cancer in humans."

U.S. Congress. Senate. Committee on Labor and Human Resources. Subcommittee on Health and Scientific Research. Saccharin ban and food safety policy, 1979. Hearing, 96th Cong., 1st sess. May 9, 1979. Washington, U.S. Govt. Print. Off., 1979. 323 p.

Weiner, Michael A., Jacqueline Cowan, and Rubin Enid. Bugs in the peanut butter: dangers in everyday food. 1st ed. Boston, Little, Brown, c1976. 112 p. TX553.A3W38 614.31.

Winter, Ruth. Cancer-causing agents: a preventive guide. New York, Crown Publishers, c1979. 250 p. RC268.6.W56 1979 616.99405.

Workplace cancers: politics vs. science. Environmental science & technology, v. 13, Jan. 1979: 15-18.

"Industry [as represented by an American Industrial Health Council paper] faults the logic and the methodology of a recent government study which attempts to estimate future cancer deaths from present and past worksite exposures."

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HOW TO SECURE ADDITIONAL MATERIAL ON CONSUMER PROTECTION

A. GENERAL INDEXES

To update or expand this compilation the debater may wish to consult such indexes as Readers' Guide to Periodical Literature and Magazine Index (a microfilm publication), guides to general and non-technical periodicals; Bulletin of the Public Affairs Information Service, a subject list of books, pamphlets, government publications, reports of research organizations, and periodical articles; Social Sciences Index, an index to selected English language journals; Index to Legal Periodicals for law journal articles; Vertical File Index, a list of free and inexpensive pamphlets, leaflets, and mimeographed materials; and the Journal of Economic Literature and Index to Business Periodicals, indexes to economics and business literature. The New York Times Index, the Wall Street Journal Index, and the Index to the Christian Science Monitor are relatively long-standing indexes to newspaper articles. More recently, the Bell & Howell Newspaper Indexing Center has compiled indexes for the Chicago Sun-Times, the Chicago Tribune, the Denver Post, the Detroit News, the Houston Post, the Los Angeles Times, the New Orleans Times-Picayune, the San Francisco Chronicle, and the Washington Post.

B. FEDERAL GOVERNMENT PUBLICATIONS

Some of the most valuable sources of information on consumer issues and developments are U.S. Government publications. Government publications available to the general public are listed in the Monthly Catalog of United States Government Publications. The Monthly Catalog provides an index to congressional hearings, reports, documents, and committee prints, as well as to publications of the executive departments. All material in this catalog is available for purchase, if still in print; or items might be obtained from your local library, from one of the over 1300 libraries serving as depository libraries for Government publications, or on interlibrary loan.

The Congressional Record contains the debates on the floors of Congress and inserted articles and speeches presented elsewhere. The Record is printed daily during sessions of Congress with a bi-weekly index. Bound volumes of the Record are published at the end of each Congress with a cumulative index for each session. Pagination differs between the daily and the bound editions. The Digest of Public General Bills and Resolutions, issued several times during each session, provides a summary of each public bill and resolution and its current status in the legislative process.

C. SOURCES COVERING CONGRESS AND THE EXECUTIVE BRANCH

Several periodical services regularly analyze current issues involving the Federal Government. Congressional Quarterly Weekly Report summarizes congressional activity for the preceding week and includes background information on issues before Congress. The Congressional Quarterly Almanac is an annual comprehensive review of the legislative session. The weekly National Journal covers recent congressional and executive branch developments and their impact. Congressional Digest features a pro-con discussion of one current legislative problem in each of ten issues per year. The Commerce Clearing House Congressional Index is a loose-leaf service reporting the status of pending legislation. The United States Code Congressional and Administrative News reproduces public laws, House and Senate reports of each bill that becomes law, legislative histories, and an essay section discussing issues before Congress.

A further aid in finding information published by Congress is CIS Annual and its monthly updates, published by the Congressional Information Service. This publication indexes and abstracts congressional hearings, reports, documents, and committee prints. Congressional materials are indexed by subject, names of hearing witnesses, authors, affiliations of witnesses, popular names of bills and reports, and law, bill, report, and document numbers.

D. CONSUMER PERIODICALS AND NEWSLETTERS

Debaters may wish to monitor on a regular basis the following list of publications in order to be aware of the latest writing on the subject of consumer protection:

Consumer Action Update (semi-monthly), U.S. Office of Consumer Affairs, 621 Reporters Building, Washington, D.C.

CFA News (10 times annually), Consumer Federation of America, 1012 14th St., N.W., Washington, D.C.

Consumer Newsweek (weekly), Consumer News, Inc., 813 National Press Building, Washington, D.C.

Family Safety (quarterly), National Safety Council, 425 Michigan Ave., Chicago, Ill.

Fire Journal (bi-monthly), National Fire Protection Assn., 470 Atlantic Ave., Boston, Mass.

Food, Drug, Cosmetic Law Journal (monthly), Commerce Clearing House, Inc., 4025 W. Peterson Ave., Chicago, Ill.

Journal of Consumer Affairs (semi-monthly), American Council on Consumer Interests, 238 Stanley Hall, University of Missouri, Columbia, Mo.

National Safety News (monthly), National Safety Council, 425 Michigan Ave., Chicago, Ill.

Of Consuming Interest, Federal-State Reports, Inc., P.O. Box 986/Court House Station, Arlington, Va.

Product Safety and Liability Reporter (weekly), Bureau of National Affairs, Inc., Washington, D.C.

Product Safety Letter (weekly), Washington Business Information, Inc., 1080 National Press Building, Washington, D.C.

E. FEDERAL AGENCIES

Below is a list of Government agencies that the debater may wish to contact for additional consumer protection information. Contact should be made with the Office of Public Information in the respective agencies.

Consumer Product Safety Commission (CPSC)
1111 18th Street, N.W.
Washington, D.C. 20207

Department of Agriculture (DOA)
The Mall, between 12th and 14th Streets, S.W.
Washington, D.C. 20250

Department of Health and Human Services (HHS)

Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857

Office of Consumer Affairs
330 Independence Ave., S.W.
Washington, D.C. 20201

Department of Housing and Urban Development (HUD)
451 7th Street, S.W.
Washington, D.C. 20410

Department of Transportation (DOT):

Federal Aviation Administration (FAA)
800 Independence Avenue, S.W.
Washington, D.C. 20591

National Highway Traffic Safety Administration (NHTSA)
400 7th Street, S.W.
Washington, D.C. 20590

U.S. Coast Guard
400 7th Street, S.W.
Washington, D.C. 20590

Environmental Protection Agency (EPA)
401 M Street, S.W.
Washington, D.C. 20460

Federal Trade Commission (FTC)
Pennsylvania Avenue at 6th Street, N.W.
Washington, D.C. 20580

General Services Administration (GSA)
Consumer Information Center
Pueblo, Co. 81009

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WASHINGTON, D.C. 20402

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PUBLICATIONS RELATING TO THE 1980-81 NATIONAL HIGH SCHOOL DEBATE TOPIC

How Can the Interests of United States Consumers Best Be Protected?

Accident at the Three Mile Island Nuclear Power Plant, Oversight Hearings Before the Subcommittee on Energy and the Environment of the Committee on Interior and Insular Affairs, On the Accident at the Three Mile Island Nuclear Power Plant, Middletown, Pennsylvania, House, 96th Congress, 1st Session, Part 1, May 9, 10, 11, and 15, 1979. 267 p.
Y 4.In 8/14:96-8/pt.1 S/N 052-070-05022-5 $ 6.00

Advertising for Over-the-Counter Drugs:

Report of the Presiding Officer on Proposed Trade Regulation Rule. 1978. 190 p.
FT 1.2:D 84/3 S/N 018-000-00231-1 3.75

Staff Report and Recommendations. 1979. 313 p.
FT 1.2:D 84/5 S/N 018-000-00250-7 7.00

Advertising of Ophthalmic Goods and Services. *Similar to the issue of Disclosure of Prescription Drug Prices, this analysis focuses on State and local restrictions in the ophthalmic field in medicine and industry, and recommends various changes to better serve the interests of the consumer.* 1976. 168 p.
FT 1.2:Op 2 S/N 018-000-00186-1 2.80

Advertising of Proprietary Medicines, Hearings Before the Subcommittee on Monopoly and Anti-Competitive Activities of the Select Committee on Small Business, Senate, 94th and 95th Congress, 1st Session: *(All missing parts are out of print.)*

Part 4, Antacids, June 6, 1973 and June 4-5, 1974. 1974. p. 1353-1672, il. Y 4.Sm 1/2:M 46/pt.4 S/N 052-070-02537-9 3.00

Part 5, Over-the-Counter Tranquilizers, Sedatives, Sleep-Aids, and Stimulants, October 29, 1975-June 21, 1977. 1977. p. 1673-1935, il.
Y 4.Sm 1/2:M 46/pt.5 S/N 052-070-04187-1 3.25

Analytical Methods for Safeguards and Accountability Measurements of Special Nuclear Materials: Proceedings From American Nuclear Society Topical Meeting Held May 15-17, 1978, Williamsburg, Virginia. 1978. 288 p. il.	C 13.10:528	S/N 003-003-01996-8	$ 4.75
Asbestos Insulation in Hand-Held Dryers, Fact Sheet 94. 1979. 3 p.	Y 3.C 76/3:11/94	S/N 052-011-00216-0	4.00 per 50
Biological Effects of Electromagnetic Waves, Selected Papers of the USNC/URSI Annual Meeting, Boulder, Colorado, October 20-23, 1975:			
Volume 1. 1976, published 1977. 494 p. il.	HE 20.4102:B 52/3/v.1	S/N 017-015-00124-5	6.50
Volume 2. 1976, published 1977. 461 p. il.	HE 20.4102:B 52/v.2	S/N 017-015-00125-3	6.25
Biological Effects of Ionizing Radiation: Pertinent Federal Laws and Regulations:			
Summary. 1979. 28 p.	HE 20.3002:R 11	S/N 017-040-00455-9	1.50
Appendix 1, Volume 1, Titles 5-30. 1979. 487 p.	HE 20.3002:R 11/app.1/v.1	S/N 017-040-00456-7	8.50
Appendix 1, Volume 2, Titles 33-50. 1979. 460 p.	HE 20.3002:R 11/app.1/v.2	S/N 017-040-00457-5	8.00
Appendix 2-3. 1979. 392 p.	HE 20.3002:R 11/app.2-3	S/N 017-040-00458-3	7.50
Bureau of Radiological Health, A Look at FDA's Program to Protect the American Consumer From Radiation. *Publication looks at a Food and Drug Administration program.* 1977. 18 p.	HE 20.4102:R 11/13	S/N 017-015-00128-8	1.20
Cancer Rates and Risks. *An accumulation of facts about cancer for physicians, medical students, teachers, and others concerned with the disease. The statistics and summaries are divided into four sections, covering cancer in the United States, distribution of various forms of cancer, factors associated with high or low cancer risks, and treatment and survival of cancer patients.* 1974. 108 p. il.	HE 20.3152:R 18/974	S/N 017-042-00086-6	1.80
Cancer Testing Technology and Saccharin. *This volume is important reading for those interested either in the use of saccharin or the validity of high-dose animal tests for carcinogens.* 1977. 149 p. il.	Y 3.T 22/2:2 C 16	S/N 052-003-00471-2	3.25

Carcinogens: Control Procedures for the Safe Handling and Use of Cancer-Causing Substances in the Workplace. *Publication reports on 14 cancer-causing substances found in the American Workplace. Contents of publication: Pt. 1, What the employer must do; Pt. 2, What the employee must know.* 1975. 19 p. il. L 35.18:17 S/N 029-015-00047-3 $ .50

Carcinogens in the Environment. *Reprinted from the Sixth Annual Report of the Council on Environmental Quality, 1976. It discusses the relationship of environmental factors to cancer, focusing on chemicals introduced into the environment by our consumption patterns and way of life.* 1976. 42 p. il. PrEx 14.1/a:C 178 S/N 041-011-00030-1 .75

Carcinogens, Regulation and Control:

Management Guide to Carcinogens, Regulation and Control. 1977. 77 p. il. HE 20.7108:C 17/2 S/N 017-033-00259-2 2.10

Working With Carcinogens, A Guide to Good Health Practices. 1977. 50 p. il. HE 20.7108:C 17 S/N 017-033-00258-4 1.90

Care Labeling of Textile Products and Leather Wearing Apparel: Staff Report to the Federal Trade Commission and Proposed Revised Trade Regulation Rule (16 CFR part 423). 1978. 481 p. FT 1.2:L 11/3 S/N 018-000-00219-1 6.75

Compilation of Laws Administered by the United States Consumer Product Safety Commission. *Contains the text of the Consumer Product Safety Act, the Flammable Fabrics Act, the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, and the Refrigerator Safety Act of 1956. Also included separately is a copy of the Consumer Product Safety Commission Improvements Act of 1976, sold separately.* 1975. 68 p. Y 3.C 76/3:5 C 73 S/N 052-011-00106-6 1.50

Compilation of Selected Acts Within the Jurisdiction of the Committee on Interstate and Foreign Commerce, Volume 4, Consumer Protection Law Including Federal Hazardous Substances Act, Fair Packaging and Labeling Act, Poison Prevention Packaging Act, Flammable Fabrics Act, Consumer Product Safety Act, Federal Caustic Poison Act, Magnuson-Moss Warranty-Federal Trade Commission Improvement Act, Federal Trade Commission Act, Motor Vehicle Information and Cost Savings Act, National Traffic and Motor Vehicle Safety Act of 1966, Refrigerator Safety Act. 1979. 324 p. Y 4.In 8/4:C 73/21/979/v.4 S/N 052-070-04884-1 4.00

Conference on Occupational Health Experience With Uranium. 1975. 476 p. ER 1.11:ERDA-93 S/N 052-010-00466-2 5.20

Consumer Aid Series:

Acceleration and Passing Ability, A Comparison of Acceleration and Passing Ability for Passenger Cars and Motorcycles for the Year 1976. 1976. 51 p. TD 8.14/2:6/pt.3 S/N 050-003-00228-3 1.65

Consumer Aid Series - con.

Brakes, A Comparison of Braking Performance for Passenger Cars and Motorcycles for the Year 1976. 1976. 25 p.
TD 8.14/2:6/pt.1 S/N 050-003-00226-7 $ .95

Tires, A Comparison of Tire Reserve Load for Passenger Cars and Motorcycles for the Year 1976. 1976. 69 p.
TD 8.14/2:6/pt.2 S/N 050-003-00227-5 1.80

Consumer Fraud: An Empirical Perspective, Summary. 1979. 78 p.
J 26.2:C 76/3 S/N 027-000-00824-1 3.50

Consumer Information Remedies: Policy Review Session. *Analyzes those Commission remedies which directly affect the quality, quantity, and variety of marketplace information.* 1979. 352 p.
FT 1.2:C 76/5 S/N 018-000-00253-1 7.50

Consumer Product Safety Act, Amendment. An Act to Amend the Consumer Product Safety Act to Extend the Authorization of Appropriations, and for Other Purposes. Approved November 10, 1978. 10 p.
GS 4.110:95/631 S/N 022-003-92162-1 .80

Consumer Products by Design, A Report on New Foods, Fabrics, and Materials From Agriculture Research. Rev. 1973. 71 p. il.
A 1.75:355/2 S/N 001-000-02790-5 1.75

Consumer Protection Act of 1977, Hearings Before the Committee on Government Affairs, Senate, 95th Congress, 1st Session, On S. 1262, To Establish an Independent Consumer Agency to Protect and Serve the Interest of Consumers, and for Other Purposes, April 19 and 20, 1977. 1977. 244 p.
Y 4.G 74/9:C 76/977 S/N 052-070-04147-1 3.25

Contrary to Nature: Being an Illustrated Commentary on Some Persons and Events of Historical Importance in the Development of Knowledge Concerning Cancer. *This is an impressive, well-researched book on the history of cancer and cancer research. It begins by examining two of the oldest written records of man, the Egyptian papyruses (written 3,500 years ago), which make references to "large tumors" on the body. It continues by describing important persons and events in the study of cancer during the Greco-Roman period, the Middle Ages, and the 16th through the 20th centuries. Most of the book is devoted to progress made since World War II. This is an excellent book for anyone interested in how knowledge concerning cancer has been developed over the years.* 1977. 498 p. il.
HE 20.3002:N 21/5 S/N 017-042-00128-5 14.75

Criteria for a Recommended Standard: Occupational Exposure During the Manufacture and Formulation of Pesticides. 1978. 429 p. il.
HE 20.7110:P 43 S/N 017-033-00314-9 6.25

Current Literature Report on the Carcinogenic Properties of Ionizing and Nonionizing Radiation:

Volume 1, Optical Radiation. 1977. 90 p. il.
HE 20.7111/2:C 11/v.1 S/N 017-033-00280-1 2.75

High School Debate . . .

Current Literature Report . . . con.

Volume 2, Microwave and Radiofrequency Radiation. 1978. 28 p. il.
HE 20.7111/2:C 11/v.2 S/N 017-033-00286-0 $ 1.50

Volume 3, Ionizing Radiation. 1978. 56 p. il.
HE 20.7111/2:C 11/v.3 S/N 017-033-00294-1 2.30

Disclosure of Energy Cost and Consumption Information in Labeling and Advertising of Consumer Appliances: Final Staff Report to the Federal Trade Commission and Recommended Rule. 1979. 257 p.
FT 1.2:L 11/5 S/N 018-000-00245-1 4.75

Don't Be Gypped. *This bulletin is designed to help the consumer avoid deceptive business practices. Also advises the consumer of help available if he has been misled, sold a shoddy product, or given poor service.* 1972. 6 p. il.
FT 1.3/2:8 S/N 018-000-00122-5 .35

Edible TV: Your Child and Food Commercials. 1977. 89 p. il.
Y 4.N 95:C 43/2 S/N 052-070-04243-5 3.00

Effect of Radiation on Human Health, Hearings Before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, On Overview of the Extent to Which the General Public Is Exposed to Radiation, the Effect of Radiation on Human Health, and to Determine Whether Existing Law Is Adequate to Protect the Public, House, 95th Congress, 2d Session, January 24, 25, 26; February 8, 9, 14, and 28, 1978, Volume 1, Health Effect of Ionizing Radiation. 1979. 1452 p. il.
Y 4.In 8/4:95-179 S/N 052-070-04845-0 10.00

Effect of Radiation on Human Health, Hearings Before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, On Concern About the Over Use of X-Rays, the Potential Health Hazards Posed by X-Rays and the Existing Levels of X-Ray Exposures Which We Now Consider Safe, House, 95th Congress, 2d Session, July 11, 12, 13, and 14, 1978, Volume 2, Radiation Health Effects of Medical and Diagnostic X-Rays. 1979. 1249 p. il.
Y 4.In 8/4:95-180 S/N 052-070-04846-8 9.00

Emergency Interim Consumer Product Safety Standard Act of 1978. An Act to Amend the Consumer Product Safety Act to Establish an Interim Consumer Product Safety Rule Relating to the Standards for Flame Resistance and Corrosiveness of Certain Insulation, and for Other Purposes. Approved July 11, 1978. 6 p.
GS 4.110:95/319 S/N 022-003-91849-3 .70

Emergency Planning Around United States Nuclear Power Plants: Nuclear Regulatory Commission Oversight. 1979. 105 p.
X 96-1:H.rp.413 S/N 052-071-00597-8 3.50

Environmental Protection Agency and the Regulation of Pesticides, Staff Report. *This is a Senate staff report that points out problems and deficiencies in EPA's pesticide programs. The introduction was written by Senator Edward Kennedy, who is a critic of the EPA in this regard.* 1976. 50 p.
Y 4.J 89/2:En 8/2 S/N 052-070-03867-5 $ .70

Evaluation of Occupational Hazards From Industrial Radiation, A Survey of Selected States. 1976, published 1977. 82 p.
HE 20.7102:R 11/2 S/N 017-033-00205-3 2.30

FDA Consumer. (Monthly except July-August and December-January which are combined issues.) *Contains information written especially for consumers about Food and Drug Administration regulatory and scientific decisions, and about the safe use of products regulated by FDA.* Subscription price: Domestic - $12.00 a year; Foreign - $15.00 a year. Single copy price: Domestic - $1.80 a copy; Foreign - $2.25 a copy. [FDAP] (File Code 2G)
HE 20.4010:

FDA Consumer Nutrition Knowledge Survey: A Nationwide Study of Food Shopper's Knowledge, Beliefs, Attitudes and Reported Behavior Regarding Food and Nutrition Labeling:

Report 1, 1973-74. 1976. 109 p. il.
HE 20.4002:N 95/3/rp.1 S/N 017-012-00265-0 3.25

Report 2, 1975. 1976. 219 p. il.
HE 20.4002:N 95/3/rp.2 S/N 017-012-00266-8 4.00

Federal Law on Consumer Deception: An Agency by Agency Analysis. 1979. 254 p. J 26.2:C 76/2 S/N 027-000-00825-9 6.00

Fluorocarbons, Technical Fact Sheet Number 1. 1975. 2 p.
Y 3.C 76/3:11-1/1 S/N 052-011-00084-1 1.75 per 50

Food Advertising:

Report of the Presiding Officer on Proposed Trade Regulation Rule. 1978. 319 p. FT 1.2:F 73/6 S/N 018-000-00212-4 5.00

Staff Report to the Federal Trade Commission on Proposed Trade Regulation Rule. 1978. 375 p.
FT 1.2:F 73/6/978 S/N 018-000-00230-2 6.00

General Services Administration Consumer Information Booklets. *These booklets are designed to tell the consumer in simple language what GSA has learned in buying products for the Government. By discussing the selection, use and maintenance of various products, these booklets will help you make better informed purchases.*

Automobile Batteries, Their Selection and Care. 1971. 13 p. il.
GS 2.16:1 S/N 022-000-00067-5 .65

GSA Consumer Information Booklets . . . con.

Carpets and Rugs. *Before buying a rug or carpet, you should have information about quality, prices, and advantages and disadvantages of different types and styles. This practical guide will help you make the best selection. It discusses common carpet fibers, texture variation, paddings, and installation.* 1973. 32 p. il.
GS 2.16:12 S/N 022-000-00080-2 .90

Household Cleaners. *Describes: all-purpose cleaners; mild cleaners; abrasives; chlorine bleaches; fabric shampoos; rug and upholstery drycleaners; wood wax and oils; leather preservatives; wall, woodwork, kitchen, bath, and metal cleaners; drain, toilet, and oven cleaners.* 1974. 12 p. il.
GS 2.16:18 S/N 022-001-00059-1 .35

Mixers and Blenders. *This consumer information booklet provides advice on what to look for when purchasing mixers and blenders. Although brand names are not mentioned, the booklet does outline the major features available in these appliances. Tips on safe use, warranties, and price guidelines are also included.* 1973. 8 p. il.
GS 2.16:13 S/N 022-000-00077-2 .35

Power Hand Tools. *Explains safety, quality, and suitability features to look for. Sections on selecting drills, drill accessories, belt sanders, finishing sanders, sander abrasives and accessories, circular saws, jig/saber saws, and saw accessories. Use of extension cords, and safe use of power tools is also covered.* 1973. 24 p. il.
GS 2.16:16 S/N 022-003-00902-7 .45

Handbook and Standard for Manufacturing Safer Consumer Products. *This publication helps industry implement the Consumer Product Safety Commission's System Standard by supplying background information regarding the rationale of its requirements as well as suggestions and ideas for its implementation.* Rev. 1977. 82 p. il.
Y 3.C 76/3:8 M 31/977 S/N 052-011-00142-2 2.30

Health and Safety Guide for Pesticide Formulators. *This booklet describes health and safety hazards and discusses proper safety practices that can minimize the hazards.* 1977. 102 p. il., 3 plates.
HE 20.7108/2:P 43 S/N 017-033-00243-6 2.00

History of the Comstock Patent Medicine Business and Dr. Morse's Indian Root Pills. 1972. 49 p. il.
SI 1.28:22 S/N 047-000-00204-4 1.30

How Consumers Use Product Information: An Assessment of Research in Relation to Public Policy Needs. 1975. 70 p.
NS 1.2:C 76/3 S/N 038-000-00237-6 1.45

Informing Workers and Employers About Occupational Cancer. *This report makes recommendations for the general content, target audience, and manner of presentation of the Occupational Cancer Information and Alert Program concerning carcinogens in the workplace.* 1977, published 1979. 16 p.
L 35.2:C 16 S/N 029-015-00053-8 1.10

Labeling and Advertising of Home Insulation: Final Staff Report to
the Federal Trade Commission and Proposed Trade Regulation Rule.
1978. [illegible]26 p. il.
FT 1.2:L 11/4 S/N 018-000-00229-9 $ 5.25

Lead Poisoning: Watch Out for Lead-Based Paint, Facts for Renters and
Purchasers. 1979. 6 p. il.
HH 1.2:L 46/5 S/N 023-000-00527-1 .75
$6.00 per 100

Legislative History of Radiation Control for Health and Safety Act of
1968. 1975. 1494 p. il. 2 volumes, sold as a set.
HE 20.4102:L 52/v.1-2 S/N 017-015-00089-3 24.00

Magnuson-Moss Warranty, Federal Trade Commission Improvement Act. An
Act to Provide Minimum Disclosure Standards for Written Consumer Product
Warranties; to Define Minimum Federal Content Standards for Such Warranties;
to Amend the Federal Trade Commission Act in Order to Improve Its Consumer
Protection Activities; and for Other Purposes. Approved January 4, 1975.
20 p. GS 4.110:93/637 S/N 022-003-90924-9 .35

Methods for Sampling and Assessing Deposits of Insecticidal Sprays Released
Over Forests. 1978. 162 p. il. Issued with plastic spiral binder.
A 1.36:1596 S/N 001-000-03866-4 4.50

National Business Council for Consumer Affairs:

Guidelines on Advertising Substantiation. 1972. 12 p.
Y 3.N 21/27:2 Ad 9 S/N 003-000-00365-5 .40

Guiding Principles for Responsible Packaging and Labeling. 1972. 8 p.
Y 3.N 21/27:8 P 12 S/N 003-010-00042-2 .55

Tire Inflation and Consumer, Program to Improve Safety and Economy.
1972. 12 p.
Y 3.N 21/27:2 T 51 S/N 052-074-00002-9 .60

National Cancer Program, Hearings Before the Committee on Government
Operations, House, 95th Congress, 1st Session:

Part 1, Overview of Program Administration, June 14, 15, 16, and 23, 1977.
1977. 858 p. il.
Y 4.G 74/7:C 16/pt.1 S/N 052-070-04264-8 6.00

Part 2, Fluoridation of Public Drinking Water, September 21 and October 12,
1977. 1977. 580 p. il.
Y 4.G 74/7:C 16/pt.2 S/N 052-070-04389-0 5.00

NIOSH (National Institute for Occupational Safety and Health) Health
Survey of Velsicol Pesticide Workers, Occupational Exposure to Leptophos
and Other Chemicals. 1978. 148 p.
HE 20.7111/2:L 55 S/N 017-033-00287-8 3.25

High School Debate . . .

Perinatal Carcinogenesis. *Conference was held in Tampa, Florida, January 19-21, 1978. Contents of publication: Human experience; Experimental studies on hormones; Nonhormonal carcinogens; Transplacental carcinogenesis in the nervous system; and Perinatal carcinogenesis and carcinogen bioassay procedures.* 1979. 282 p. il. Clothbound.
HE 20.3162:51 S/N 017-042-00139-1 $10.00

Pesticides Abstracts. (Monthly and Annual Index.) *Monthly publication of the United States Environmental Agency which fosters current awareness of the major worldwide literature on effects of pesticides. Reviews more than 2,000 domestic and foreign sources. Periodicals from which articles have been abstracted are listed in each January issue. Subjects and authors of abstracted articles are cross-referenced in March, June, September, and the annual index issue.* Subscription price: Domestic - $21.00 a year; Foreign - $26.25 a year. Single copy price: Domestic - $1.60 a copy; Foreign - $2.00 a copy. Annual Index: Domestic - $1.80 a copy; Foreign - $2.30 a copy. [HAPS] (File Code 2M)
EP 5.9:

Pesticides Monitoring Journal. (Quarterly.) *Interagency publication of the National Pesticide Monitoring Program which publishes Federal findings on pesticide levels in humans and all other elements of the environment. Includes extensive tables of monitoring data. Accepts monitoring studies from State and local governments, universities, private industry and foreign nations. Appears in March, June, September, and December; subject/author index is in March issue.* Subscription price: Domestic - $7.90 a year; Foreign - $9.90 a year. Single copy price: Domestic - $2.00 a copy; Foreign - $2.50 a copy. [PMOJ] (File Code 2Q)
PrEx 14.9:

Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station (A Preliminary Assessment for the Period March 28 Through April 7, 1979). *This publication outlines the findings of an Ad Hoc Population Dose Assessment Group. It presents an assessment of the collective radiation dose received by the population and addresses several areas of concern about the type of radiation released, the contribution to population exposure due to beta radiation, the degree of coverage afforded by available radiation measurements, and the range of health effects that may result from the estimated collective dose.* 1979. 99 p. il.
Y 3.N 88:2 P 81 S/N 017-001-00408-1 3.75

Practitioner's Guide to the Diagnostic X-Ray Equipment Standard. *The Federal Diagnostic x-ray standard is aimed at reducing patient exposure during x-ray examinations. This booklet outlines the major provision of the standard, summarizes practitioner responsibilities, discusses upgrading used equipment and provides answers to 13 frequently asked questions about the standard.* Rev. 1978. 11 p.
HE 20.4108:X 1/5/978 S/N 017-015-00147-4 .80

Price of Death, A Survey Method and Consumer Guide for Funerals, Cemeteries, and Grave Markers. 1975. 35 p.
FT 1.8/3:3 S/N 018-000-00185-3 1.05

Procedures for Field Testing Microwave Ovens. *Gives procedures for testing ovens for compliance with the microwave emission and safety interlock operation requirements of the Federal radiation safety performance standard. The manual is useful for Food and Drug Administration, State and local testing personnel.* 1977. 35 p. il.
HE 20.4108:M 58 S/N 017-015-00138-5 $ 1.60

Radiation Hazard in Mining. *Deals with the occurence of lung cancer among underground miners caused by breathing radioactive dust particles known as radon daughters.* 1977. 30 p. il.
I 69.8/2:7 S/N 024-019-00025-0 1.50

Radioactivity in Consumer Products. 1979. 509 p.
Y 3.N 88:27/00001 S/N 052-010-00503-1 6.50

Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968. *Contains regulations published in the Federal Register through September 1978 for Code of Federal Regulations, Title 21, Chapter I, Subchapter J, Part 1000, 1002-1005, 1010, 1020, 1030, 1040, and 1050.* Rev. 1978. 68 p. il.
HE 20.4106:R 11/978 S/N 017-012-00274-9 2.50

Regulations Under the Federal Hazardous Substances Act, Technical Fact Sheet Number 4. 1975. 5 p.
Y 3.C 76/3:11-2/4 S/N 052-011-00087-6 3.50 per 50

Resolved, That the Federal Government Should Significantly Strengthen the Guarantee of Consumer Product Safety Required of Manufacturers, Selected Excerpts and References Relating to the Intercollegiate Debate Topic for 1976-77. 1976. 298 p. il.
X 94-2:H.doc.656 S/N 052-071-00509-9 2.80

Safe Handling of Radioactive Materials: Recommendations of the National Committee on Radiation Protection. 1964. 107 p. il.
C 13.11:92 S/N 003-003-00136-8 2.10

Safe Toys for Your Child, How to Select Them, How to Use Them Safely. 1971. 8 p. il.
HE 21.110:473 S/N 017-091-00159-6 .35

Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets. *This is a Bureau of Economics study of product differentiation and its relationship to brand promotion and brand sales. The study focused on two therapeutic markets for prescription drugs. It sought to determine the validity of the widely-held notion that leading brands gain and retain market dominance primarily as a result of promotional activity.* 1977. 164 p.
FT 1.2:D 84/2 S/N 018-000-00207-8 2.75

High School Debate . . .

Survey of Compounds Which Have Been Tested for Carcinogenic Activity:

1961-1967 Volume, Section 1 and Section 2. 1973. 4666 p. il.
Clothbound. 2 sections, sold as a set.
HE 20.3152:C 17/961-67 S/N 017-042-00050-5 $48.75

Supplement 2. 1969. 655 p. il. Clothbound.
HE 20.3152:C 17/supp.2 S/N 017-042-00024-6 13.35

Survey of Consumer Fraud Law. 1978. 216 p. il.
J 1.2:C 76/13 S/N 027-000-00672-8 4.25

Survey of Photocopier and Related Products. *Examines optical radiation, radiation control and radiation protection in connection with photocopier equipment and related products.* 1978. 67 p. il.
HE 20.4102:P 56/6 S/N 017-015-00149-1 2.50

Suspected Carcinogens, A Subfile of the NIOSH Registry of Toxic Effects of Chemical Substances, 2d Edition. 1976. 251 p. il.
HE 20.7112/2:C 17/976 S/N 017-033-00224-0 4.50

Take a Closer Look, The Consumer Product Safety Commission Openness Policy. 1977. 12 p. il.
Y 3.C 76/3:2 L 87 S/N 052-011-00120-1 4.50 per 25

Television Advertising to Children. *Discusses petitions from Action for Children's Television, and the Center for Science in the Public Interest, requesting the promulgation of a trade rule regulating television advertising of candy and other sugared products to children.* 1978. 365 p.
FT 1.2:T 23/2 S/N 018-000-00228-1 6.00

Vinyl Chloride, Fact Sheet 58. 1975. 2 p.
Y 3.C 76/3:11/58 S/N 052-011-00056-6 1.75 per 50

We Want You to Know About:

Diagnostic X-Rays. 1973. 8 p. il.
HE 20.4002:X 1 S/N 017-012-00181-5 .35

Labels on Medicines. Rev. 1976. 6 p. il.
HE 20.4002:M 46/3/976 S/N 017-012-00237-4 .35

Your Federal Trade Commission, What It Is and What It Does. 1977.
26 p. il. FT 1.2:F 31/6/976 S/N 018-000-00199-3 .55

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